

EXHIBIT C

<p style="text-align: right;">Page 1</p> <p>1 UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY</p> <p>2 ----- X</p> <p>3 IN RE: VALSARTAN, LOSARTAN, AND : MDL NO. 2875 IRBESARTAN PRODUCTS LIABILITY : LITIGATION, : 4 : THIS DOCUMENT RELATES TO: : 5 Duffy, et al. v. Solco Healthcare : U.S., L.L.C., et al., : 6 Case No. 1:18-cv-15076-RBK-JS : ----- X</p> <p>7 8 9 VOLUME II ***RESTRICTED CONFIDENTIAL***</p> <p>10 11 12 Veritext Virtual Zoom Videotaped 13 deposition of MAHYAR ETMINAN, taken on Wednesday, 14 August 25, 2021, held in Vancouver, City of British 15 Columbia, Canada, commencing at 8:32 a.m., before 16 Jamie I. Moskowitz, a Certified Court Reporter and 17 Certified Livenote Reporter.</p> <p>18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S: (All appearances via Zoom)</p> <p>2</p> <p>3 GREENBERG TRAUIG BY: STEPHEN T. FOWLER, ESQUIRE 4 2101 L Street, N.W. - Suite 1000 Washington, DC 20037 5 202.331.3100 fowlerst@gtlaw.com 6 Counsel for Defendant Teva Pharmaceuticals Industries Ltd.</p> <p>7</p> <p>8 GREENBERG TRAUIG BY: STEVEN M. HARKINS, ESQUIRE 9 Terminus 200 3333 Piedmont Road NE - Suite 2500 10 Atlanta, Georgia 30305 678.553.2100 11 harkins@gtlaw.com Counsel for Defendant Teva Pharmaceuticals 12 Industries Ltd.</p> <p>13</p> <p>14 HILL WALLACK LLP BY: NAKUL Y. SHAH, ESQUIRE 21 Roszel Road 15 Princeton, New Jersey 08540 609.924.0808 16 nshah@hillwallack.com Counsel for the Defendants Hetero Drugs and Hetero 17 Labs</p> <p>18 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP 19 BY: JASON M. REEFER, ESQUIRE BY: CLEM C. TRISCHLER, ESQUIRE 20 One Oxford Centre 301 Grant Street -- Floor 38 21 Pittsburgh, Pennsylvania 15219 412.263.2000 22 jmr@pietragallo.com Counsel for the Defendant Mylan</p> <p>23 24 25</p>
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<p style="text-align: right;">Page 5</p> <p>1 2 A P P E A R A N C E S: (All appearances via Zoom) 3 4 FALKENBERG IVES LLP BY: MEGAN A. ZMICK, ESQUIRE 5 230 West Monroe Street - Suite 2220 Chicago, Illinois 60606 6 312.566.4801 maz@falkenbergives.com 7 Counsel for the Defendant Humana Pharmacy 8 9 ALSO PRESENT: 10 JUSTIN BILEY Legal Videographer and Concierge 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 7</p> <p>1 REQUEST PAGE 2 INSTRUCTIONS NOT TO ANSWER: 3 Page Line 4 None 5 REQUEST FOR PRODUCTION OF DOCUMENTS: 6 Page Line Description 7 None 8 STIPULATIONS: 9 Page Line 10 None 11 QUESTIONS MARKED: 12 Page Line 13 None 14 15 16 17 18 19 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 6</p> <p>1 EXHIBITS 2 3 EXHIBIT NUMBER DESCRIPTION PAGE 4 EX 28 Document 76 5 EX 29 Search criteria 77 6 EX 30 Bradford Hill criteria 107 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 8</p> <p>1 TABLE OF CONTENTS 2 MAHYAR ETMINAN 3 Examination 4 By Mr. Gallagher.....Page 9 5 By Mr. Trischler.....Page 9 6 By Ms. Kapke.....Page 60 7 By Mr. Fowler.....Page 63 8 Notice to Read & Sign.....Page 120 9 Reporter Certificate.....Page 122 10 Index of Exhibits.....Page 6 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

<p style="text-align: right;">Page 9</p> <p>1 THE VIDEOGRAPHER: The time is now 2 8:32. This is a continuation of 3 Mahyar Etminan's deposition. We are back on 4 the record. 5 EXAMINATION BY MR. GALLAGHER: 6 Q Good morning, Dr. Etminan. 7 A Good morning. 8 Q At this time, I don't -- at this time 9 I don't have further questions for you. Some of the 10 other defense counsel do, so I'm going to turn it 11 over to counsel for Mylan. 12 EXAMINATION BY MR. TRISCHLER: 13 Q Good morning, Doctor. 14 A Good morning. 15 Q I'll just start by introducing myself 16 to you. My name's Clem Trischler. I represent the 17 Mylan defendants in this litigation. I'll be asking 18 you some questions following up on Mr. Gallagher. 19 If you can -- if you have any trouble 20 hearing me, please let me know so I can rephrase or 21 repeat the question. Okay? 22 A Okay. 23 Q Let me start by asking you this 24 relatively simple and straightforward question, 25 Doctor. Would you agree with me that NDMA and NDEA</p>	<p style="text-align: right;">Page 11</p> <p>1 on a daily basis? 2 A No, not personally. 3 Q Have you done any original research in 4 your career that's been designed to determine or 5 calculate the baseline daily exposure to NDEA? 6 A No. 7 Q Are you aware of the fact that there 8 are studies that have been published in the 9 peer-reviewed literature that suggest that dietary 10 intake of NDEA and NDMA can be as high as 2,000 11 nanograms per day for the average American? 12 MR. NIGH: Form objection. 13 THE WITNESS: That -- I mean, that's 14 possible. I don't remember of a specific 15 paper, but that's possible. 16 BY MR. TRISCHLER: 17 Q Okay. And are you aware of the same 18 studies suggesting that smokers have a daily intake 19 of NDEA and NDMA that can be as high as 20,000 -- 20 25,000 nanograms per day? 21 A I'm not aware of studies, but it's 22 possible that's the case. 23 MR. NIGH: Form objection to that 24 question. 25</p>
<p style="text-align: right;">Page 10</p> <p>1 are ubiquitous? 2 MR. NIGH: Form objection. 3 THE WITNESS: Yes, generally speaking. 4 BY MR. TRISCHLER: 5 Q Those compounds are found virtually 6 everywhere, true? 7 MR. NIGH: Form objection. 8 THE WITNESS: Generally speaking, yes. 9 BY MR. TRISCHLER: 10 Q NDMA and NDEA are found in the air we 11 breathe, in the water we drink and in the food we 12 eat, correct? 13 A Yes. 14 Q In fact, I think you wrote in your 15 report that NDMA and NDEA are found in pesticides, 16 hair dye, air, water and food. That's what you 17 wrote I think on Page 7 of your report, right? 18 A Yes. 19 Q So it's a known fact that each and 20 every one of us are exposed to nitrosamines such as 21 NDMA and NDEA on a daily basis, true? 22 A Yes. 23 Q And as part of your work in this case, 24 have you attempted to quantify the baseline level of 25 exposure to NDEA that the average American receives</p>	<p style="text-align: right;">Page 12</p> <p>1 BY MR. TRISCHLER: 2 Q Assuming there are studies that 3 suggest daily intake of nitrosamines for smokers can 4 be as high as 20,000 to 25,000 nanograms per day, do 5 you have any scientific basis to dispute that fact? 6 MR. NIGH: Form objection. 7 THE WITNESS: Well, I mean I have 8 to -- I have to read the scientific paper and 9 then see exactly how that number was derived. 10 So I think you're asking me a very general 11 question. 12 BY MR. TRISCHLER: 13 Q Well, I don't know whether it's 14 general or specific. I'm just asking you a 15 question, and the question is this: As you sit here 16 today providing testimony under oath, are you aware 17 of any evidence to suggest that daily intake of 18 nitrosamines for smokers is something other than 20 19 to 25,000 nanograms per day on average? 20 MR. NIGH: Form objection. 21 THE WITNESS: I -- I don't -- I didn't 22 look at nitrosamine exposure among smokers, so, 23 again, this is -- this is not an area that I 24 specifically looked at. I know generally 25 speaking, smokers could have a higher</p>

<p style="text-align: right;">Page 13</p> <p>1 concentration of NDMA than nonsmokers.</p> <p>2 BY MR. TRISCHLER:</p> <p>3 Q And I think what you said as part of</p> <p>4 your research in this case and part of your work in</p> <p>5 this case, you did not do any analysis to determine</p> <p>6 baseline exposures for either NDEA or NDMA, right?</p> <p>7 MR. NIGH: Form objection.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MR. TRISCHLER:</p> <p>10 Q Would you agree that if an individual</p> <p>11 consumes alcohol, his or her daily exposure to NDEA</p> <p>12 and NDMA would be expected to increase?</p> <p>13 A Than a nonalcoholic, yes.</p> <p>14 Q Well, not just a known alcoholic, but</p> <p>15 anyone that consumes alcoholic. I like a beer or</p> <p>16 two from time to time, and I don't think I'm an</p> <p>17 alcoholic. But when I consume alcohol, research</p> <p>18 suggests that my daily intake of nitrosamines is</p> <p>19 going to go up. Wouldn't you agree?</p> <p>20 A It's -- yeah, it's going to go -- it's</p> <p>21 going to be higher than, you know, when you were not</p> <p>22 taking alcohol or compared to somebody who's not</p> <p>23 taking alcohol.</p> <p>24 Q Sure, so -- so we can agree that</p> <p>25 there's a baseline of exogenous exposure to NDEA and</p>	<p style="text-align: right;">Page 15</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. TRISCHLER:</p> <p>3 Q Nothing in your report that's been</p> <p>4 filed with the court in this case quantifies</p> <p>5 baseline NDEA or NDMA exposures, agreed?</p> <p>6 MR. NIGH: Object to form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. TRISCHLER:</p> <p>9 Q And at the outset of yesterday when</p> <p>10 you were being asked questions by Mr. Gallagher,</p> <p>11 what I recall you stating is that what you were</p> <p>12 retained to do was to review the literature and</p> <p>13 provide an answer to the question of whether NDMA,</p> <p>14 regardless of route of administration, could</p> <p>15 plausibly cause cancer in humans. That was the</p> <p>16 question you were asked, and you -- and you</p> <p>17 undertook a literature review to try to answer that</p> <p>18 question, correct?</p> <p>19 A Yes.</p> <p>20 Q And while that was the question you</p> <p>21 were asked to evaluate, I think, as we have just</p> <p>22 established, there were other questions concerning</p> <p>23 NDMA and NDEA that you never examined, right?</p> <p>24 A Well, what do you mean by "other</p> <p>25 questions"?</p>
<p style="text-align: right;">Page 14</p> <p>1 NDMA that all of us experience, right?</p> <p>2 A Yes.</p> <p>3 Q All of us have a lifetime of exposures</p> <p>4 to NDMA and NDEA, right?</p> <p>5 A Yes.</p> <p>6 Q Every plaintiff in this litigation has</p> <p>7 been exposed to NDMA and NDEA throughout their</p> <p>8 lifetimes just like you and I have, right?</p> <p>9 A Yes.</p> <p>10 Q In this case, though, you've done</p> <p>11 nothing to independently assess, evaluate or</p> <p>12 quantify what that baseline exposure is, right?</p> <p>13 MR. NIGH: Form objection.</p> <p>14 THE WITNESS: You're talking about me</p> <p>15 undertaking a study, looking at your question.</p> <p>16 That was not what I did or I was asked to do.</p> <p>17 BY MR. TRISCHLER:</p> <p>18 Q I understand. That's what I'm just</p> <p>19 trying to clarify. There were things were you asked</p> <p>20 to do and things you were not.</p> <p>21 And one of the things you have not</p> <p>22 done is to quantify a baseline exposure for NDEA and</p> <p>23 NDMA for any plaintiff in this litigation or any</p> <p>24 average person in the community, right?</p> <p>25 MR. NIGH: Form objection.</p>	<p style="text-align: right;">Page 16</p> <p>1 Q Well, for instance, we talked about</p> <p>2 the fact that you never researched the amounts of</p> <p>3 NDMA that the average American adult consumes on a</p> <p>4 daily basis, right?</p> <p>5 A I do have in my report a citation of</p> <p>6 general range of exposure of NDMA in -- you know, in</p> <p>7 the American diet. And I agree with you that, you</p> <p>8 know, generally, they are all exposed to NDMA, you</p> <p>9 know, from the environment or from air or what have</p> <p>10 you.</p> <p>11 Q Right. And I think you agreed with me</p> <p>12 that daily exposure is on the order of</p> <p>13 2,000 nanograms per day. But my question was that</p> <p>14 was not the -- determining that average baseline</p> <p>15 exposure from dietary intake was not the question</p> <p>16 that you were asked to answer?</p> <p>17 MR. NIGH: Hold on. Hold on. Object</p> <p>18 to form, mischaracterizes his testimony. Never</p> <p>19 was there an agreement that the average</p> <p>20 baseline is 2,000 nanograms of NDMA.</p> <p>21 You can answer.</p> <p>22 MR. TRISCHLER: I don't think speaking</p> <p>23 objections are permitted, Daniel, so please</p> <p>24 don't do it.</p> <p>25 MR. NIGH: Well, you can't</p>

<p style="text-align: right;">Page 17</p> <p>1 mischaracterize testimony.</p> <p>2 MR. TRISCHLER: Well, I think you can</p> <p>3 object to form, but let's not -- let's not</p> <p>4 start testifying, please.</p> <p>5 MR. NIGH: Okay. Form objection.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. TRISCHLER:</p> <p>8 Q And you never researched the amount of</p> <p>9 NDEA that the average American consumes on a daily</p> <p>10 basis, right?</p> <p>11 A Yes.</p> <p>12 Q You have not reviewed the cases of any</p> <p>13 plaintiff in this litigation to calculate their</p> <p>14 cumulative -- cumulative lifetime exposure to NDMA</p> <p>15 or NDEA prior to the time they consumed any</p> <p>16 valsartan-containing medication, right?</p> <p>17 A Correct.</p> <p>18 Q Have you ever -- we have been talking</p> <p>19 about exogenous exposure, but have you ever</p> <p>20 independently researched endogenous formation of</p> <p>21 nitrosamines where the extent of endogenous</p> <p>22 formation that occurs prior to the time you were</p> <p>23 retained in this case?</p> <p>24 A No.</p> <p>25 Q And in connection with your work in</p>	<p style="text-align: right;">Page 19</p> <p>1 published by a gentleman named Jakszyn as the lead</p> <p>2 author -- lead author, excuse me. Jakszyn is</p> <p>3 spelled J-a-k-s-z-y-n, I believe. Do you recall</p> <p>4 that paper?</p> <p>5 A Yes.</p> <p>6 Q I think it was entitled "Endogenous</p> <p>7 Versus Exogenous Exposure to Nitroso Compounds" and</p> <p>8 was marked as Exhibit 12, yesterday. Do you</p> <p>9 remember that?</p> <p>10 A Right.</p> <p>11 Q And according to that paper by</p> <p>12 Jakszyn, we're exposed to over 93,000 nanograms of</p> <p>13 nitrosamines every single day. Do you remember</p> <p>14 that?</p> <p>15 MR. NIGH: Form objection.</p> <p>16 THE WITNESS: I do remember that.</p> <p>17 BY MR. NIGH:</p> <p>18 Q And as part of your work in this case,</p> <p>19 you have not done any independent research studies</p> <p>20 or testing to -- to suggest or establish that the</p> <p>21 estimates of total nitrosamine exposure as predicted</p> <p>22 by Jakszyn were incorrect, fair to say?</p> <p>23 A Yes.</p> <p>24 Q And I trust you'd agree with me that</p> <p>25 if you want to evaluate the impact of nitrosamines</p>
<p style="text-align: right;">Page 18</p> <p>1 this case, have you ever done any research to try</p> <p>2 and answer the question of the extent of endogenous</p> <p>3 formation of nitrosamines that occurs in the human</p> <p>4 body?</p> <p>5 A No. I mean, that -- that is not my</p> <p>6 field of expertise.</p> <p>7 Q Understood.</p> <p>8 Are you aware of any research</p> <p>9 suggesting that all of us endogenously form</p> <p>10 nitrosamines in our body at levels even higher than</p> <p>11 what we consume exogenously?</p> <p>12 A I know that there is potential for</p> <p>13 endogenous formation of NDMA in -- in the human</p> <p>14 body.</p> <p>15 Q Right. And in reading some of the</p> <p>16 studies that you cite in your report, and that you</p> <p>17 were kind enough to discuss with us yesterday, some</p> <p>18 of those studies suggest that the level of</p> <p>19 nitrosamines that form endogenously are far greater</p> <p>20 than what we consume on a daily basis, right?</p> <p>21 MR. NIGH: Form objection.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. TRISCHLER:</p> <p>24 Q In fact, I think one of the papers</p> <p>25 that was cited in your report was a paper that was</p>	<p style="text-align: right;">Page 20</p> <p>1 in valsartan-containing medications, what we need to</p> <p>2 consider is the extent to which individual</p> <p>3 consumption of NDMA and NDEA increase due to the</p> <p>4 presence of those compounds in the drugs, right?</p> <p>5 MR. NIGH: Form objection.</p> <p>6 THE WITNESS: I mean, if you want to</p> <p>7 do a perfect study, yes, that's -- that's what</p> <p>8 needs to be done.</p> <p>9 BY MR. TRISCHLER:</p> <p>10 Q And in assessing carcinogenicity of</p> <p>11 any compound, you agree that dose and duration of</p> <p>12 exposure are always important, right?</p> <p>13 A Generally speaking, yes.</p> <p>14 Q Right. Well, in fact, yesterday, we</p> <p>15 discussed the Pottgard and Gomm studies. Do you</p> <p>16 remember that?</p> <p>17 A Yes.</p> <p>18 Q And one of the things I remember from</p> <p>19 your testimony yesterday was that you were critical</p> <p>20 of those studies because the amount of NDMA exposure</p> <p>21 was not specified in the controls. Do you recall</p> <p>22 telling us that?</p> <p>23 A Yes.</p> <p>24 Q And you told us that, you know, for</p> <p>25 that -- in that study, you would have liked to have</p>

<p style="text-align: right;">Page 21</p> <p>1 seen the controls broken down by high exposure, 2 medium exposure and low exposure. Do you remember 3 telling us that? 4 A Yes. 5 Q And the inference from that is that 6 you wanted them broken down that way because dose 7 and duration are undoubtedly important and 8 undoubtedly contribute to carcinogenicity, right? 9 A Yes. 10 MR. NIGH: Form objection. 11 BY MR. TRISCHLER: 12 Q And in this case, you've been very 13 clear and very honest and open in telling us that 14 you have not done any work to -- since you have not 15 done any work to establish baseline exposures, 16 right? 17 MR. NIGH: Form objection. 18 THE WITNESS: Yes, I think I have 19 answered that already. 20 BY MR. TRISCHLER: 21 Q Right. And since you have not done 22 any work to establish baselines, you can't tell us 23 the extent to which any plaintiff's daily intake of 24 NDMA or NDEA increased due to the use of 25 valsartan-containing medications, right?</p>	<p style="text-align: right;">Page 23</p> <p>1 Q And the -- as part of your work in 2 this case, did you -- did you calculate the mean 3 parts per million that was observed in Mylan's 4 product? 5 A I remember I may have calculated 6 either the mean or the -- or the higher range of the 7 PPM. 8 Q Well, if you calculated a mean, what 9 did you calculate? 10 A I don't remember off the top of my 11 head. But I mean, if I can just do a quick 12 calculation if you tell me what the -- if I can -- 13 I'm just looking at my report. 14 Q Well, to calculate the mean, you'd 15 need to know a lot more than just what the lower 16 bound and what the upper bound of the range was, 17 right? 18 A Yes. 19 Q Right. And the only information you 20 have in your report is the low -- low range being 21 .01 parts per million, and the high being 1.57 parts 22 per million -- per million. So how would you 23 calculate a mean? But you can't calculate a mean 24 based on that. You'd need other data and other 25 information.</p>
<p style="text-align: right;">Page 22</p> <p>1 A Correct. 2 Q So if we -- I told you at the outset I 3 introduced myself, my client is Mylan. If we use 4 Mylan is an example. You reference my client I 5 think only in one place in that -- in your -- 6 THE COURT REPORTER: I'm sorry. You 7 cut out. 8 BY MR. TRISCHLER: 9 Q I said you reference Mylan only in one 10 place in your entire report. Would you agree? 11 A I believe it's the -- the part where I 12 show the ranges of -- of NDMA in the product. 13 Q Agreed. 14 You -- you -- you provided us with a 15 40-page report, and the only place where you ever 16 mention my client is in a footnote on Page 8, 17 correct? 18 A Yes. I wasn't asked to write reports 19 for different manufacturers. 20 Q I understand. But in that footnote, 21 you suggest that NDEA concentrations in some of 22 Mylan's products were found to range from .01 parts 23 per million to 1.57 parts per million. Do you 24 remember writing that? 25 A Yes.</p>	<p style="text-align: right;">Page 24</p> <p>1 A Yeah, I probably -- I probably just -- 2 MR. NIGH: Hold on. Hold on. Let me 3 object to the form first. Form objection. 4 You can answer, Doctor. 5 THE WITNESS: I probably only looked 6 at the higher -- higher end of the 1.57. 7 BY MR. TRISCHLER: 8 Q So -- so your best recollection, 9 sitting here today, is you never calculated a mean 10 concentration of NDEA in the Mylan product, right? 11 A Right. 12 Q Well, I'll represent to you that 13 the -- for purposes of my questions that the mean 14 concentration for -- in Mylan's product is observed 15 to be 0.047 parts per million, okay? 16 A Okay. 17 Q And if we assume the -- did you -- 18 were you made aware of the fact that the largest 19 concentration in which valsartan-containing 20 medications or the largest dose in which 21 valsartan-containing medications were made available 22 in the United States was 320 milligrams per day? 23 A Yes. 24 Q And so if the mean is .047 parts per 25 million, and we assume the largest dose of</p>

<p style="text-align: right;">Page 25</p> <p>1 320 milligrams, that results in a mean exposure of</p> <p>2 150 nanograms, correct?</p> <p>3 A Correct.</p> <p>4 Q So going back to Jakszyn's data in</p> <p>5 Exhibit 12 that you -- in his paper that you</p> <p>6 included with your report, if his estimate of</p> <p>7 nitrosamine exposure of 93,000 nanograms per day is</p> <p>8 accurate, in 150 nanogram --</p> <p>9 THE COURT REPORTER: I'm sorry. You</p> <p>10 broke up. You broke up.</p> <p>11 MR. TRISCHLER: I'll start over.</p> <p>12 BY MR. TRISCHLER:</p> <p>13 Q If we assume the data from Jakszyn's</p> <p>14 paper is accurate, then adding a 150-nanogram</p> <p>15 exposure to a daily nitrosamine exposure of 93,000</p> <p>16 nanograms is miniscule, correct?</p> <p>17 MR. NIGH: Object to form. Object to</p> <p>18 form.</p> <p>19 THE WITNESS: Well, again, we --</p> <p>20 that's -- the Jakszyn study is one study. It</p> <p>21 has some limitations. Back to your -- back to</p> <p>22 your point, the 150, I believe the -- the Mylan</p> <p>23 nanogram per -- the mean Mylan nanogram per day</p> <p>24 of 150 is -- one has to look at this as a</p> <p>25 cumulative exposure. So patients would be</p>	<p style="text-align: right;">Page 27</p> <p>1 MR. TRISCHLER: Objection, move to</p> <p>2 strike as nonresponsive.</p> <p>3 BY MR. TRISCHLER:</p> <p>4 Q Let's see if we can try this again,</p> <p>5 Doctor.</p> <p>6 A 150-nanogram exposure is miniscule</p> <p>7 compared to a 93,000-nanogram exposure, right?</p> <p>8 MR. NIGH: Object to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. TRISCHLER:</p> <p>11 Q It's .01 percent of the total</p> <p>12 exposure, simple math, right?</p> <p>13 MR. NIGH: Object to form.</p> <p>14 THE WITNESS: Yes, but you are -- you</p> <p>15 are -- you're assuming that the -- that there</p> <p>16 is one patient taking -- exposed to endogenous</p> <p>17 X amount -- I don't know if the Jakszyn study</p> <p>18 is -- is the true endogenous value. But let's</p> <p>19 say there is an X amount of endogenous NDMA in</p> <p>20 one person. That person is being -- is adding</p> <p>21 to that, cumulatively, an extra dose. You're</p> <p>22 assuming that the other people who are not</p> <p>23 taking that extra dose do not have endogenous</p> <p>24 exposure, and only that patient has endogenous</p> <p>25 plus exogenous exposure.</p>
<p style="text-align: right;">Page 26</p> <p>1 taking this over extended period of time. 150</p> <p>2 is still higher than the -- the recommended or</p> <p>3 the allowable daily dose by the FDA.</p> <p>4 And you are sort of assuming that only</p> <p>5 the patient who's taking the 150-nanogram Mylan</p> <p>6 dose has that endogenous exposure -- sort of</p> <p>7 exposure to endogenous nitrosamines as well.</p> <p>8 In other words, you know, in the population, as</p> <p>9 we spoke earlier, we are all exposed to</p> <p>10 nitrosamines. So population-wise, there is no</p> <p>11 reason to believe that the people who are not</p> <p>12 taking that extra dose of Mylan also do not</p> <p>13 have endogenous exposure to NDMA.</p> <p>14 What I'm trying to say is that</p> <p>15 endogenous exposure in the population is</p> <p>16 probably very similar, at least in the American</p> <p>17 population, based on the diet. And if a</p> <p>18 patient is taking an extra dose of 150</p> <p>19 nanograms per day of Mylan or any other</p> <p>20 exposures, an extra dose added to that baseline</p> <p>21 dose, which again is higher than the</p> <p>22 recommended daily dose by the FDA, cumulatively</p> <p>23 over a long period of time, it is possible that</p> <p>24 that dose could potentially increase the risk</p> <p>25 of cancer.</p>	<p style="text-align: right;">Page 28</p> <p>1 What I'm trying to say that in a</p> <p>2 population, as we discussed, where diets are</p> <p>3 pretty stable, and this is in the U.S., for the</p> <p>4 most part, most people will have that baseline</p> <p>5 endogenous exposure. So the person who's</p> <p>6 taking the exogenous NDMA in valsartan, you'll</p> <p>7 have -- you'll have an added extra risk if</p> <p>8 you're taking it cumulatively every day.</p> <p>9 So that -- that's what I was trying to</p> <p>10 explain to you.</p> <p>11 BY MR. TRISCHLER:</p> <p>12 Q I think I understand, Doctor. I'm not</p> <p>13 making the assumption that you believe I am. I</p> <p>14 agree with you 100 percent, that every one of us has</p> <p>15 exogenous and endogenous exposures to nitrosamines.</p> <p>16 And if Jakszyn is correct, that that exposure is on</p> <p>17 the order of 93,000 nanograms per day.</p> <p>18 And so my -- so the issue in this</p> <p>19 case, then, is does an exposure of an extra</p> <p>20 150-nanograms representing a .01 percent increase in</p> <p>21 that exposure level result in a substantial --</p> <p>22 statistically significant increased risk of cancer.</p> <p>23 That's the question I want to answer.</p> <p>24 And what I'm asking hearing from you</p> <p>25 is that's not a question -- I haven't asked the</p>

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1 question. That's not a question you ever answered
 2 in this case. You certainly don't answer it in your
 3 report, right?
 4 MR. NIGH: Hold on. Object to the
 5 colloquy, argumentative.
 6 You can answer.
 7 THE WITNESS: So, again, as I
 8 mentioned yesterday, I'd love to answer that
 9 question. But the -- the type of question
 10 you're asking, data for that question, good
 11 data, is not available. What I was asked to do
 12 is to answer the question as a general
 13 causation question, does exposure to NDMA over
 14 time increase the risk of cancer. So that's
 15 what I -- that's what my systematic review
 16 addressed.
 17 BY MR. TRISCHLER:
 18 Q Understood.
 19 A I did not -- I did not address mostly
 20 because I -- you know, I did search for the data.
 21 But that specific question that you're asking -- and
 22 it's quite more of an individual -- you know,
 23 individual causation question rather than a general
 24 causation question. So I did not answer that, the
 25 type of question you're asking.

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1 Q Well, I agree with a lot of what you
 2 said. I disagree that it's not a general causation
 3 question.
 4 But I think what we can really agree
 5 on is your statement that good data does not exist
 6 to answer the question of whether an incremental
 7 increase in nitrosamine exposures above the baseline
 8 that we all experience will lead to a statistically
 9 significant increased risk of cancer. It's not a
 10 question that you answered, and the data is not
 11 there to answer it. That's what you just told us
 12 under oath, right?
 13 MR. NIGH: Object to form.
 14 You can answer.
 15 THE WITNESS: Again, I -- in my
 16 report, I -- I was asked to answer whether
 17 there is general causation with exposure to
 18 NDMA over time. That's what I answered in my
 19 report.
 20 BY MR. TRISCHLER:
 21 Q And you did not answer the question of
 22 whether an incremental increase over some period
 23 of -- over some period less than lifetime would lead
 24 to a statistically significant increased risk of
 25 cancer because the data is not there to answer that

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1 question, agreed?
 2 MR. NIGH: Object to the form.
 3 You can answer.
 4 THE WITNESS: I answered the question
 5 that NDMA exposure over time increases the risk
 6 of cancer. I did not answer the question of
 7 incremental increase, and I really don't
 8 understand what you mean by "statistically
 9 significant."
 10 But I did not answer the question
 11 whether incremental increase of any specific
 12 doses of NDMA increased the risk of cancer. I
 13 answered a more general question of exposure,
 14 exposure over time versus cancer risk.
 15 BY MR. TRISCHLER:
 16 Q In your review of the scientific
 17 literature, did you find a single cohort or case
 18 control study that reported that a 1 to 2-percent
 19 increase in daily NDMA exposure would lead to a
 20 statistically significant increased risk of
 21 esophageal cancer?
 22 MR. NIGH: Object to form.
 23 THE WITNESS: Can you repeat the
 24 question, please?
 25 BY MR. TRISCHLER:

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1 Q In your review of the scientific
 2 literature, did you find a single cohort or case
 3 control study that reported that a 1 to 2-percent
 4 increase in daily NDMA exposure would lead to a
 5 statistically significant increased risk of
 6 esophageal cancer?
 7 MR. NIGH: Object to form.
 8 THE WITNESS: I don't know if the
 9 study looked at 1 to 2-percent increase, but
 10 there are -- the dietary studies that I
 11 included have looked at sort of a dose response
 12 exposure of NDMA per day, looking at high
 13 versus low doses with respect to cancer.
 14 BY MR. TRISCHLER:
 15 Q Can you cite me any study, as you sit
 16 here today, where the authors looked at incremental
 17 increases in nitrosamine exposure and concluded that
 18 a 1 to 2-percent increase in NDMA or NDEA intake
 19 would lead to an increased risk of cancer?
 20 A Can you clarify --
 21 MR. NIGH: Hold on. Hold on. Object
 22 to the form.
 23 You can answer.
 24 THE WITNESS: Can you clarify what you
 25 mean by "incremental increase"?

<p style="text-align: right;">Page 33</p> <p>1 BY MR. TRISCHLER:</p> <p>2 Q What I'm -- what we've been talking</p> <p>3 about, Doctor, that we all have a baseline of -- of</p> <p>4 exposure that we have been receiving on a daily</p> <p>5 basis. Let's assume that that baseline exposure is</p> <p>6 2,000-nanograms. If we were exposed to</p> <p>7 2,000-nanograms for the first 40 years of our life,</p> <p>8 and then in year 41, we begin to -- that exposure</p> <p>9 increases to 2,100 nanograms per day, what I want to</p> <p>10 know is: Are there any studies to suggest that an</p> <p>11 incremental increase in daily nitrosamine exposure</p> <p>12 is expected to lead to an increased risk of cancer?</p> <p>13 MR. NIGH: Hold on. Hold on. Hold</p> <p>14 on. Hold on. Object to the form.</p> <p>15 THE WITNESS: What I think you're --</p> <p>16 you're referring to is whether -- whether there</p> <p>17 is a dose response increase with NDMA exposure</p> <p>18 and cancer so that the more NDMA you take over</p> <p>19 a period, your risk of cancer is higher.</p> <p>20 So again, some of the dietary studies</p> <p>21 that I've discussed have looked at subjects who</p> <p>22 have taken the highest cumulative dose of NDMA</p> <p>23 in their diet and compared them to the -- to</p> <p>24 the lowest, considering that all of those --</p> <p>25 all of that population is also exposed to some</p>	<p style="text-align: right;">Page 35</p> <p>1 not have looked at nitrosamines in the way</p> <p>2 you're asking the question. But they have</p> <p>3 looked at those response. You're -- you're</p> <p>4 basically saying does somebody who has an</p> <p>5 increase in 1 to 2 percent over five years,</p> <p>6 does that person have a higher risk of cancer,</p> <p>7 and I think what -- and I think what you mean,</p> <p>8 and correct me if I'm wrong, is compared to</p> <p>9 somebody who doesn't have that 1 to 2 percent</p> <p>10 increase. That -- that is a dose response</p> <p>11 question, and I'm -- and that has been looked</p> <p>12 at in the dietary studies, not -- not exactly</p> <p>13 the way you have put it. But they have looked</p> <p>14 at cumulative dosing.</p> <p>15 BY MR. TRISCHLER:</p> <p>16 Q Well, I'm -- well, the way you phrased</p> <p>17 the question is the way I'm looking for you to</p> <p>18 answer it, Doctor.</p> <p>19 And -- and so my question is, tell me</p> <p>20 the -- name me the dietary study where it says that</p> <p>21 a slight, short duration increase in nitrosamine</p> <p>22 exposure is gonna increase your risk for developing</p> <p>23 cancer. I can -- I read your papers, the papers you</p> <p>24 sent. I can't find it, so tell me where it is.</p> <p>25 MR. NIGH: Object to form. This is</p>
<p style="text-align: right;">Page 34</p> <p>1 level of endogenous NDMA through their diet.</p> <p>2 They have looked at exogenous NDMA</p> <p>3 using dietary measures and looked at that dose</p> <p>4 response. So I think, again, your -- I think</p> <p>5 your question is whether there's a dose</p> <p>6 response relation. And I have shown in my</p> <p>7 report that some of these dietary studies have</p> <p>8 shown a dose response.</p> <p>9 BY MR. TRISCHLER:</p> <p>10 Q That's not -- that wasn't my question,</p> <p>11 but let me -- so let me try to ask it again.</p> <p>12 Name me a study that's in your report</p> <p>13 or that you uncovered in your research that</p> <p>14 establishes that there is an increased risk of</p> <p>15 cancer if my nitrosamine intake is increased by</p> <p>16 5 percent for a period of five years.</p> <p>17 MR. NIGH: Sorry. Was that the end of</p> <p>18 the question?</p> <p>19 MR. TRISCHLER: Yes.</p> <p>20 MR. NIGH: Okay. Object to form.</p> <p>21 THE WITNESS: Again, I think -- I</p> <p>22 think you're asking -- I think your question is</p> <p>23 asking the same concept of a dose response in a</p> <p>24 different fashion.</p> <p>25 And so again, if -- the studies may</p>	<p style="text-align: right;">Page 36</p> <p>1 getting argumentative, lots of colloquy. It's</p> <p>2 inappropriate. It's not a question.</p> <p>3 MR. TRISCHLER: It's a question. It</p> <p>4 might not be a good one, Dan, but it's a</p> <p>5 question.</p> <p>6 MR. NIGH: But the -- "I've read your</p> <p>7 report. I can't find out where it is." You</p> <p>8 know, that's not a question. That's</p> <p>9 argumentative. It's inappropriate.</p> <p>10 THE WITNESS: Again, the -- the -- the</p> <p>11 dose response analysis done in the dietary</p> <p>12 studies look at or present a dose response</p> <p>13 relation. They have not looked at it the way</p> <p>14 you have portrayed your question or the way you</p> <p>15 want the dose response to be looked at. But</p> <p>16 they have addressed -- I still think that your</p> <p>17 question -- your question is a dose response</p> <p>18 question. And they have addressed dose</p> <p>19 response in the way that all dietary studies</p> <p>20 address them, high dose versus low dose. What</p> <p>21 is the risk? Is there a difference in risk?</p> <p>22 BY MR. TRISCHLER:</p> <p>23 Q And what you're saying -- what you're</p> <p>24 suggesting with your answer is the same thing I</p> <p>25 think we already talked about, and that is that dose</p>

<p style="text-align: right;">Page 37</p> <p>1 and duration do matter, correct?</p> <p>2 A Yes.</p> <p>3 Q Right. And so what I'm trying to</p> <p>4 define is when does the dose and duration exposure</p> <p>5 to nitrosamines lead to an increased risk of cancer?</p> <p>6 Where do we draw the line? You have cited in your</p> <p>7 report -- you have got 71 references listed in this</p> <p>8 report, correct?</p> <p>9 A Yes.</p> <p>10 Q Tell me by number which one of those</p> <p>11 71 references that I can go to that is going to</p> <p>12 suggest that if I increase my daily nitrosamine</p> <p>13 exposure by 5 percent or less for some period of</p> <p>14 time, that I'm -- I'm at an increased risk for</p> <p>15 cancer? Does that -- does that data exist anywhere?</p> <p>16 MR. NIGH: Objection.</p> <p>17 THE WITNESS: Again, the -- the way --</p> <p>18 the question that you're asking me, that --</p> <p>19 that type of analysis, I -- I did not find.</p> <p>20 But I did include, as you mentioned, dietary</p> <p>21 studies of the dose response analysis.</p> <p>22 BY MR. TRISCHLER:</p> <p>23 Q We talked about the fact that all of</p> <p>24 us are exposed to NDMA and NDEA on a regular basis</p> <p>25 true?</p>	<p style="text-align: right;">Page 39</p> <p>1 done it. And I was not -- that's not what I was</p> <p>2 asked to do.</p> <p>3 Q Are you familiar with the concept of</p> <p>4 permissible daily exposure?</p> <p>5 A Yes.</p> <p>6 Q Is it true that permissible daily</p> <p>7 exposure is defined as a dose that's unlikely to</p> <p>8 cause an adverse effect if the individual is exposed</p> <p>9 at or below that dose for a lifetime?</p> <p>10 A I believe that's what it stands for.</p> <p>11 Q Okay. Have you ever calculated a</p> <p>12 permissible daily exposure for any nitrosamine?</p> <p>13 A No, because I relied on the</p> <p>14 epidemiologic studies that I looked at. I mean, the</p> <p>15 permissible daily exposure mostly comes from animal</p> <p>16 data.</p> <p>17 Q I'm just asking if you have ever</p> <p>18 calculated a PDE for any nitrosamine?</p> <p>19 A No. I appreciate that, but I just</p> <p>20 need to be able to explain myself. So, no, I have</p> <p>21 not.</p> <p>22 Q Do you agree there is one though,</p> <p>23 right?</p> <p>24 A There is one, for example, the FDA has</p> <p>25 one, yes.</p>
<p style="text-align: right;">Page 38</p> <p>1 A Correct.</p> <p>2 Q But we can agree that while all of us</p> <p>3 are exposed to NDMA and NDEA every day, not all of</p> <p>4 us are going to develop cancer, correct?</p> <p>5 A Yes.</p> <p>6 Q So there's obviously a threshold dose</p> <p>7 or a threshold exposure at which NDMA and NDEA will</p> <p>8 not cause harm, agreed?</p> <p>9 MR. NIGH: Object to form.</p> <p>10 THE WITNESS: I -- I don't know. I</p> <p>11 don't know the answer to that question.</p> <p>12 BY MR. TRISCHLER:</p> <p>13 Q You have never calculated a threshold</p> <p>14 dose for NDEA, have you?</p> <p>15 A Well, you're -- your question is not</p> <p>16 about the threshold dose on NDMA -- NDEA. I believe</p> <p>17 your question is whether there is a threshold dose</p> <p>18 in causing cancer, and so that requires another</p> <p>19 study. It's not as simple as just calculating</p> <p>20 threshold dose.</p> <p>21 BY MR. TRISCHLER:</p> <p>22 Q Well, I'm just asking you if you've</p> <p>23 ever done it.</p> <p>24 A No, because that requires, again, a</p> <p>25 very large sophisticated study, and I -- I have not</p>	<p style="text-align: right;">Page 40</p> <p>1 Q Well, the FDA has an acceptable intake</p> <p>2 level that it's established for nitrosamine levels</p> <p>3 in drug products, but that's not a PDE, is it?</p> <p>4 MR. NIGH: Object to form.</p> <p>5 THE WITNESS: It may not be. I'll</p> <p>6 have to -- I'd have to check.</p> <p>7 BY MR. TRISCHLER:</p> <p>8 Q Well, just think about it. We've</p> <p>9 already -- we've already talked about and</p> <p>10 established that nitrosamines are ubiquitous and</p> <p>11 we're exposed to them from lots of sources, not just</p> <p>12 drugs, right?</p> <p>13 A Yes.</p> <p>14 Q Right. So there's a -- there's a</p> <p>15 permissible daily exposure for all nitrosamines</p> <p>16 including NDMA and NDEA. You've -- but you've not</p> <p>17 determined what they are, correct?</p> <p>18 MR. NIGH: Object to form.</p> <p>19 THE WITNESS: I don't know -- I mean,</p> <p>20 I could have during my research, but it doesn't</p> <p>21 ring a bell right now.</p> <p>22 BY MR. TRISCHLER:</p> <p>23 Q And you don't recall seeing any data</p> <p>24 suggesting a PDE for NDEA or NDMA, right?</p> <p>25 A Correct.</p>

<p style="text-align: right;">Page 41</p> <p>1 Q Are you aware of any research that's</p> <p>2 been published in the peer-reviewed literature</p> <p>3 suggesting that a short-term increase in NDEA or</p> <p>4 NDMA exposure above the PDE will lead to an</p> <p>5 increased risk of cancer in humans?</p> <p>6 MR. NIGH: Object to form.</p> <p>7 THE WITNESS: No.</p> <p>8 BY MR. TRISCHLER:</p> <p>9 Q So if I could summarize what I</p> <p>10 understand your work in this case to be, Doctor, is</p> <p>11 that -- your focus was on addressing the general</p> <p>12 question of whether the literature supports a</p> <p>13 plausible causal connection between NDMA and cancer</p> <p>14 in humans, right?</p> <p>15 MR. NIGH: Object to form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. TRISCHLER:</p> <p>18 Q I didn't hear your answer because of</p> <p>19 the objection.</p> <p>20 A Yes.</p> <p>21 Q And your -- your research was not</p> <p>22 focused on dose or duration or on examining the</p> <p>23 impact of incremental increases in daily exposures,</p> <p>24 right?</p> <p>25 MR. NIGH: Object to form.</p>	<p style="text-align: right;">Page 43</p> <p>1 Q Okay. Had you ever participated in</p> <p>2 any epidemiological studies involving NDEA?</p> <p>3 A No.</p> <p>4 Q Had you ever participated in any</p> <p>5 animal study -- or excuse me. Have you ever</p> <p>6 participated in any epidemiological studies</p> <p>7 involving NDMA?</p> <p>8 A No.</p> <p>9 Q Prior to the time the plaintiffs'</p> <p>10 lawyers knocked on your door to ask you to work on</p> <p>11 this case, had you ever done any work in your</p> <p>12 professional career with nitrosamines?</p> <p>13 A No.</p> <p>14 Q So is it fair to say that in your</p> <p>15 career as a -- in the fields of pharmacology and</p> <p>16 epidemiology, that you never researched, studied or</p> <p>17 investigated the possible association of</p> <p>18 nitrosamines and cancers before you were retained in</p> <p>19 this case?</p> <p>20 A I have done studies in the past on</p> <p>21 carcinogens and cancer, but not specifically on</p> <p>22 nitrosamines.</p> <p>23 Q Right. And so since you had no</p> <p>24 specific background in studying, researching or</p> <p>25 investigating nitrosamines, the only basis for your</p>
<p style="text-align: right;">Page 42</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. TRISCHLER:</p> <p>3 Q And now I want to ask you some</p> <p>4 questions specifically about NDEA. Before you were</p> <p>5 retained in this case, had you ever done any</p> <p>6 original clinical research on the carcinogenicity of</p> <p>7 NDEA?</p> <p>8 A No.</p> <p>9 Q For that matter, before you were</p> <p>10 retained by the plaintiffs' lawyers in this case,</p> <p>11 had you ever done any original clinical research on</p> <p>12 the carcinogenicity of NDMA?</p> <p>13 A No.</p> <p>14 Q Had you ever published any</p> <p>15 peer-reviewed studies assessing or evaluating the</p> <p>16 carcinogenicity of NDEA in humans?</p> <p>17 A No.</p> <p>18 Q Had you ever published any</p> <p>19 peer-reviewed studies assessing or evaluating the</p> <p>20 carcinogenicity of NDMA in humans?</p> <p>21 A No.</p> <p>22 Q Had you ever done any animal studies</p> <p>23 or participated in any animal studies looking at the</p> <p>24 carcinogenicity of any nitrosamine?</p> <p>25 A No. I'm not a basic scientist, so no.</p>	<p style="text-align: right;">Page 44</p> <p>1 opinion as to whether NDMA or NDEA can cause cancer</p> <p>2 in humans is the literature that -- review that you</p> <p>3 did in connection with this case, right?</p> <p>4 A Yes.</p> <p>5 MR. NIGH: Object to form.</p> <p>6 BY MR. TRISCHLER:</p> <p>7 Q And in the -- with that literature</p> <p>8 review, I want to ask you specifically about NDEA.</p> <p>9 Did you identify in your literature</p> <p>10 review any observational study in the literature</p> <p>11 that found a statistically significant association</p> <p>12 between NDEA and breast cancer?</p> <p>13 A Specifically on breast cancer?</p> <p>14 Q Yes, NDEA and breast cancer.</p> <p>15 A No.</p> <p>16 Q In your research for purposes of this</p> <p>17 case, did you -- can you identify any observational</p> <p>18 study that you found in the literature that reported</p> <p>19 a statistically significant association between NDEA</p> <p>20 and esophageal cancer?</p> <p>21 A No.</p> <p>22 Q In connection with your work in this</p> <p>23 case, can you identify for me any observational</p> <p>24 study in the literature that found a statistical --</p> <p>25 statistically significant association between NDEA</p>

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1 and stomach cancer?
2 A No.
3 Q In connection with your work in this
4 case, can you identify any observational study that
5 you found in the literature that found a
6 statistically significant association between NDEA
7 and colorectal cancer?
8 A No.
9 Q In connection with your work in this
10 case, can you identify any observational study in
11 the literature that found a statistically
12 significant association between NDEA and liver
13 cancer?
14 A No.
15 Q In connection with your work in this
16 case, can you identify any observational study in
17 the literature that found a statistically
18 significant association between NDEA and lung
19 cancer?
20 A No.
21 Q In connection with your work in this
22 case, can you identify any observational study that
23 found a statistically significant association
24 between NDEA and bladder cancer?
25 A No.

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1 Q In connection with your work in this
2 case, can you identify any observational study
3 published in the literature that found a
4 statistically significant association between NDEA
5 and prostate cancer?
6 A No.
7 Q In connection with your work in this
8 case, can you identify any observational study
9 reported in the literature with a statistically
10 significant association between NDEA and blood
11 cancers?
12 A No.
13 Q In connection with your work in this
14 case, can you identify any observational studies
15 published in the literature that found a
16 statistically significant association between NDEA
17 and pancreatic cancer?
18 A I identified one study by Zheng that
19 looked at NDEA and found an increase in risk.
20 Q And that -- that paper was -- the lead
21 author was Zheng, Z-h-e-n-g, correct?
22 A That's right.
23 Q And that was published in 2018 in a
24 publication called "Carcinogenesis"?
25 A Yes.

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1 Q And would you agree with me that even
2 while finding an association between pancreatic
3 cancer and NDEA, the authors of the Zheng paper were
4 careful to note that their observations were
5 preliminary?
6 A That's what they may have stated in
7 their paper, yes.
8 Q And isn't it true that the authors of
9 that paper were careful to note that the findings
10 and this reported association between NDEA and
11 pancreatic cancer was merely preliminary?
12 A If that's what they said in their
13 paper, then that's what they said, but -- I mean,
14 that's what --
15 Q Well, you read -- you read it. Do you
16 recall?
17 A I have read a lot of these papers. I
18 can read it now. I don't recall that statement,
19 but --
20 Q Isn't it true that the authors of the
21 Zheng paper noted that their findings were
22 preliminary and needed to be confirmed in a large
23 prospective cohort study with consideration of
24 sufficient time between diet assessment and disease
25 diagnosis?

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1 MR. NIGH: Object to form.
2 THE WITNESS: That is -- they are sort
3 of portraying a perfect scenario. I'm not sure
4 if -- and they call this preliminary. I'm not
5 sure if there will ever be a large prospective
6 study looking at this question again, but
7 that's what they state.
8 BY MR. TRISCHLER:
9 Q Well, that was going to be my next
10 question. Do you -- are you aware of the large
11 prospective cohort study that Zheng and his
12 colleagues recommended to be done, whether it was
13 ever done?
14 MR. NIGH: Object to form.
15 THE WITNESS: I'm not aware.
16 BY MR. TRISCHLER:
17 Q We talked about my client,
18 Mylan Pharmaceuticals, a bit and how you mentioned
19 them in that footnote on Page 8.
20 Can we agree that nowhere in your
21 40-page report that you filed in this case did you
22 ever conclude that an increase in NDEA intake in the
23 amounts contained in Mylan's valsartan-containing
24 medication to cause cancer in humans?
25 MR. NIGH: Can you repeat that? You

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1 broke up. You broke up at the end.
 2 MR. TRISCHLER: Sure.
 3 MR. NIGH: Thank you.
 4 BY MR. NIGH:
 5 Q Can we agree that nowhere in your
 6 report you ever conclude that an increase in NDEA
 7 intake in the amounts contained in Mylan's
 8 valsartan-containing medications was sufficient to
 9 cause cancer in humans?
 10 A Yes.
 11 Q And you -- and in your work in this
 12 case, you have not found a single study in the
 13 peer-reviewed literature that would support a
 14 statistically significant increased risk of any
 15 cancer from a short-term duration nitrosamine intake
 16 increase of 150 nanograms per day, right?
 17 A You mean a specific study that -- that
 18 looks at that specific dosage and cancer?
 19 Q Yes.
 20 A No.
 21 Q The -- the -- are you familiar with
 22 the concept of latency periods in cancer?
 23 A Yes.
 24 Q Do you know what the average latency
 25 period is for esophageal cancer?

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1 A Specifically for esophageal cancer,
 2 no.
 3 Q Do you know the average latency period
 4 for stomach cancer?
 5 A No.
 6 MR. NIGH: Object to form.
 7 BY MR. TRISCHLER:
 8 Q Do you know the average latency period
 9 for colorectal cancer?
 10 MR. NIGH: Object to form.
 11 THE WITNESS: The latency period for
 12 cancer in general is usually around, give or
 13 take, ten years.
 14 BY MR. TRISCHLER:
 15 Q All right. I'm asking about specific
 16 cancer types, and if you don't know, you can simply
 17 tell me you don't know.
 18 A Right. Again, I'm not an oncologist.
 19 So no, I -- I -- the answer to your question -- the
 20 last -- the answer to your last question on stomach
 21 latency is I don't know.
 22 Q Okay. So and if I went through the
 23 nine cancer types that you mention in your report,
 24 would you know the average latency period for any of
 25 them?

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1 MR. NIGH: Object to form.
 2 THE WITNESS: Not specifically.
 3 BY MR. TRISCHLER:
 4 Q We talked a little bit about the
 5 Gomm -- or you talked a little bit about the Gomm
 6 and Pottgard studies yesterday. And we mentioned
 7 them again this morning. You're familiar with those
 8 papers, right?
 9 A Yes.
 10 Q And I think one of the things that you
 11 indicated to us was that you were critical of the
 12 observations by Gomm and Pottgard in their papers
 13 because the study durations too short; is that
 14 correct?
 15 A Yes.
 16 Q Basically what you -- what you said
 17 was that a study duration of -- with a study
 18 duration on the order of three, four and five years,
 19 it was simply too early to tell whether or not
 20 nitrosamines in valsartan-containing medications
 21 might have an increased risk of cancer, right? You
 22 need more time?
 23 A Well, for a population-based study, it
 24 is short. But that doesn't mean that, you know, in
 25 some patients, a shorter onset of cancer cannot

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1 occur. But when I'm looking at a -- obviously, this
 2 was a population study, the ones you're mentioning.
 3 And for a population study that median of
 4 three years is short.
 5 Q I wasn't asking you about whether
 6 there's any particular individual that might have a
 7 shorter latency period than another. I was asking
 8 you about study design.
 9 And what you told us yesterday was
 10 that a study period of four or five years, which I
 11 believe is the time frame in the Pottgard and Gomm
 12 studies is just too short, and it's too early to
 13 tell whether or not nitrosamines in
 14 valsartan-containing medications can cause an
 15 increased risk of cancer; you need a longer period
 16 of time to study that, right?
 17 A Yes.
 18 MR. NIGH: Object to form. Hold on.
 19 Hold on. Object to form. That was asked and
 20 answered.
 21 BY MR. TRISCHLER:
 22 Q That's what you told us yesterday,
 23 right?
 24 A Yes.
 25 Q Okay. And so in your opinion, how

<p style="text-align: right;">Page 53</p> <p>1 long would you have to go out to find a credible 2 study that evaluates NDMA and NDEA in 3 valsartan-containing medications and whether those 4 medications lead to an increased risk of cancer? 5 MR. NIGH: Form objection. 6 THE WITNESS: Certainly, more than, 7 you know, five years. 8 BY MR. TRISCHLER: 9 Q Okay. What does that mean? Does it 10 mean six years is enough, or do you have to go to 11 like 10, 15? 12 A Well, again, you're asking me a 13 technical question. So one has to sit down, and if 14 you're looking at different types of cancer, you 15 have to factor in the -- the different latencies of 16 all the cancers that you want to study and then make 17 sure that the follow-up period that you have in your 18 study design meets those latency periods. 19 Q Okay. So are you familiar with a 20 paper by Nadler, N-a-d-l-e-r, entitled, "Estimating 21 Cancer Latency Times Using Weibull," W-e-i-b-u-l-l, 22 "Model"? 23 A Doesn't ring a bell. 24 Q Are you familiar with the Weibull 25 model?</p>	<p style="text-align: right;">Page 55</p> <p>1 average latency period in the literature. And I 2 asked if you have any basis to dispute it. 3 MR. NIGH: Object to form. 4 THE WITNESS: No, I have no basis to 5 dispute it or agree to it. 6 BY MR. TRISCHLER: 7 Q Okay. And in -- in the same paper, 8 the authors estimate the average latency period of 9 lung cancer to be 13 years. Do you have any basis 10 to dispute that? 11 MR. NIGH: Object to form. 12 THE WITNESS: Again, I can't agree or 13 dispute. 14 BY MR. NIGH: 15 Q And so if we wanted to -- if we were 16 an epidemiologist like yourself and we wanted to 17 carry out, you know, a well-designed epidemiological 18 study to evaluate whether nitrosamines in 19 valsartan-containing medications led to an increased 20 risk of stomach cancer, we'd need to carry that 21 study out for 22 years, right? 22 MR. NIGH: Object to form. 23 BY MR. TRISCHLER: 24 Q If we assume that's the correct 25 latency period?</p>
<p style="text-align: right;">Page 54</p> <p>1 A Yes. 2 Q What is it? 3 A A Weibull model is -- I believe it's a 4 parametric statistical model. 5 Q For estimating latency periods? 6 A I -- again, that's a technical 7 statistical question, but I believe it could be. 8 It's a very general model that's used for different, 9 sort of, outcomes and -- and one -- I mean, it could 10 possibly be used for statistical modeling of latency 11 as well. Because it looks at time, and latency is a 12 time. You know, it's a function of time. 13 Q So I'll represent to you that in 14 this -- in the Nadler paper using the Weibull model 15 to estimate cancer latency times, the authors 16 concluded that the average latency period for 17 stomach cancer is 22 years. You don't have any 18 information to dispute that, right? 19 MR. NIGH: Object to form. 20 THE WITNESS: I'm not going to agree 21 right now on the latency period, which is quite 22 a complex topic, based on just one paper. 23 BY MR. TRISCHLER: 24 Q I didn't ask you to agree to it. I 25 asked you -- I made a representation to you of the</p>	<p style="text-align: right;">Page 56</p> <p>1 MR. NIGH: Object to form. 2 THE WITNESS: It -- it will be -- it 3 should be a study that has a very long follow 4 up. Again, I don't want to be agreeing on 5 numbers that -- that I haven't seen or from one 6 paper. But generally speaking, it needs a long 7 period of follow up. 8 BY MR. NIGH: 9 Q And so if we're going to be -- if 10 we're going to approach the question of whether 11 nitrosamines in valsartan-containing medications 12 lead to an increased risk of cancer, we're going to 13 make that determination based on the science, what 14 you're telling us is we just don't know at this 15 point because the -- we don't have enough time to 16 answer the question, right? 17 MR. NIGH: Object to form. 18 THE WITNESS: To specifically design a 19 study that looks at oral nitrosamine, it's 20 going to be a complex study. But again, my 21 report and my review was on a general causation 22 of exposure of nitrosamine -- nitrosamines and 23 cancer. 24 BY MR. TRISCHLER: 25 Q By the way, there are -- there are a</p>

<p style="text-align: right;">Page 57</p> <p>1 few other cancer types that are at issue in this 2 litigation, breast cancer, kidney cancer, pharyngeal 3 cancer and uterine cancer. 4 In your report, you did not observe 5 any statistically significant increased risk between 6 NDMA and NDEA exposure and breast cancer, do you? 7 A Again, I don't think a statistically 8 significant increase is the right sort of portrayal. 9 I did not include any studies, whether significant 10 or not, because they did not meet -- those types 11 studies did not meet my inclusion criteria, which -- 12 Q So you don't -- I'm sorry. I didn't 13 mean to interrupt you. 14 A Go ahead. 15 Q No. I thought you were finished. 16 A I -- sorry. I think I am finished. 17 Q I guess what I'm asking is you do not 18 intend to offer an opinion that NDMA exposure or 19 NDEA exposure will lead to an increased risk of 20 breast cancer, do you? 21 A No, because it's a not in my report, 22 and I did not cover -- cover this topic. 23 Q You do not intend to offer an opinion 24 that exposure to NDMA or NDEA lead to an increased 25 risk of kidney cancer, do you?</p>	<p style="text-align: right;">Page 59</p> <p>1 THE WITNESS: Can we take a break now 2 if you have more information to cover, but if 3 you're reaching the end, maybe we can continue. 4 Either option is okay. 5 MR. TRISCHLER: Well, I'm -- I'm 6 reaching my end, but there will be another 7 examiner, at least one other examiner that I'm 8 aware of. So we can take a break. 9 THE WITNESS: No, I understand. I 10 meant just your section. 11 MR. TRISCHLER: Yeah. You won't -- 12 you won't -- we can take a break whenever you 13 want. It won't mess me up, so you're in 14 control of that. So you tell me. 15 THE WITNESS: I mean, if you have 16 another 5, 10 minutes, we can go -- you know, 17 we can continue. If it's longer, I'd like to 18 take a break. 19 MR. TRISCHLER: No, I don't have 20 any -- in fact, I think -- I think I'm probably 21 finished, so I will pass the witness. If you 22 want to take a break now then, or, you know, 23 I'll leave that up to you and Daniel. 24 THE WITNESS: Sure. Can I take a 25 break, everyone?</p>
<p style="text-align: right;">Page 58</p> <p>1 A No. 2 Q You do not intend to offer an opinion 3 that exposure to NDMA or NDEA lead to an increased 4 risk of pharyngeal cancer, do you? 5 A Well, I do have -- I do have oral 6 cancers including larynx, I believe, in my report. 7 So pharyngeal, specifically no, but I do talk about 8 oral cancers, in general, including the larynx. And 9 so, again, I do make an opinion on oral cancers in 10 general. It does not specifically say pharyngeal. 11 Q Okay. But when you say "oral 12 cancers," the only one I'm aware of that arguably 13 constitute oral, at least as I understand the 14 anatomy, is esophageal? 15 A No. Oral cancers can also include the 16 mouth, the esophagus and also the pharynx and the 17 larynx. So I do have a section in my report on 18 pharynx, larynx and the esophagus, which I combine 19 into head and neck cancers. 20 Q Okay. Do you intend to offer an 21 opinion that exposure to NDMA or NDEA increase the 22 risk of uterine cancer? 23 A No. 24 THE WITNESS: Can I interject? 25 MR. TRISCHLER: Yes.</p>	<p style="text-align: right;">Page 60</p> <p>1 MR. NIGH: Yeah, let's take a 2 ten-minute break. 3 THE VIDEOGRAPHER: The time is now 4 9:34. This ends Media Unit Number 1. We're 5 going off the record. 6 (Whereupon, a short break was taken.) 7 THE VIDEOGRAPHER: The time is now 8 9:49 in this begins Media Unit Number 2 we're 9 back on the record. 10 EXAMINATION BY MS. KAPKE: 11 Q Good morning, Dr. Etminan. My name's 12 Kara Kapke, and I just have a few short questions. 13 You talked about how the -- one of the 14 questions you were answering was whether NDMA or 15 NDEA exposure over time increases the risk of 16 cancer. Can you quantify the duration of time that 17 you're talking about? 18 MR. NIGH: Form objection. 19 THE WITNESS: Different studies have 20 different durations. So I can't really give 21 you a specific answer. 22 I believe that -- in the range from 23 maybe three or four years up to the study -- 24 the occupational study, I believe had a 35 or 25 40-year follow up, so it is a big range.</p>

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<p>1 BY MS. KAPKE:</p> <p>2 Q So given that -- your answer, is it</p> <p>3 fair to say that a person would need to take NDMA or</p> <p>4 NDEA containing valsartan for at least three years</p> <p>5 before they had an increased risk of cancer?</p> <p>6 MR. NIGH: Object to form.</p> <p>7 THE WITNESS: No, I -- I wouldn't say</p> <p>8 that because, again, every -- it's a very --</p> <p>9 latency to cancer is very individualized. And</p> <p>10 those are median follow-ups -- you -- which</p> <p>11 means that you have -- at each end -- you have</p> <p>12 a lower end and a higher end. So I can't -- I</p> <p>13 don't really want to make that specific sort of</p> <p>14 statement.</p> <p>15 BY MS. KAPKE:</p> <p>16 Q What are you willing to say, to a</p> <p>17 reasonable degree of scientific certainty, that is</p> <p>18 the -- minimum amount of time that a person would</p> <p>19 need to have taken valsartan that contained NDMA or</p> <p>20 NDEA before they are subject to an increased risk of</p> <p>21 cancer?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 THE WITNESS: Again, given that I</p> <p>24 looked at general causation, I can say that</p> <p>25 exposure to NDMA and NDMA valsartan increases</p>	<p>1 Similar type of question, but what does "systemic"</p> <p>2 mean to you?</p> <p>3 A Systemic means that NDMA that's</p> <p>4 available in -- in the body, and it's absorbed and</p> <p>5 available in the body to, you know, all the organs.</p> <p>6 All the organs are subject to some level of NDMA.</p> <p>7 Q And have you ever put a quantification</p> <p>8 of the dose or the duration that it takes to reach</p> <p>9 that systemic exposure?</p> <p>10 MR. NIGH: Form objection.</p> <p>11 THE WITNESS: Can you repeat the</p> <p>12 question, please?</p> <p>13 MS. KAPKE: Can the court reporter</p> <p>14 read it back?</p> <p>15 (Whereupon, the testimony was read</p> <p>16 back as requested.)</p> <p>17 THE WITNESS: No.</p> <p>18 MS. KAPKE: Thank you very much,</p> <p>19 Dr. Etminan. I'll pass the witness.</p> <p>20 THE WITNESS: Thank you.</p> <p>21 EXAMINATION BY MR. FOWLER:</p> <p>22 Q Good day, Dr. Etminan.</p> <p>23 You may have seen me briefly</p> <p>24 yesterday. Let me just reintroduce myself. I'm</p> <p>25 Steve Fowler with the law firm Greenberg Traurig,</p>
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<p>1 the risk of cancer over time. I don't have any</p> <p>2 specific data to, sort of, give you a specific</p> <p>3 number right now.</p> <p>4 BY MS. KAPKE:</p> <p>5 Q You would agree with me that a person</p> <p>6 who took a single pill for -- you know, one -- one</p> <p>7 pill of valsartan that contained NDMA or NDEA would</p> <p>8 not have an increased risk of cancer, correct?</p> <p>9 A One pill over what period?</p> <p>10 Q One day.</p> <p>11 A No.</p> <p>12 Q You don't agree or you do agree with</p> <p>13 that?</p> <p>14 A I agree with you that taking one pill</p> <p>15 of valsartan for one day does not increase the risk</p> <p>16 of cancer.</p> <p>17 Q What about 30 days, so 30 days' worth</p> <p>18 of pills?</p> <p>19 A 30 days, probably not as well.</p> <p>20 Q I'm going to push it out. How about</p> <p>21 90 days?</p> <p>22 A Again, less likely.</p> <p>23 Q Another way you -- you framed the</p> <p>24 question that you are evaluating was whether</p> <p>25 systemic exposure to NDMA could cause cancer.</p>	<p>1 and we represent the Teva defendants. I've got some</p> <p>2 additional questions for you.</p> <p>3 But let me just start very quickly.</p> <p>4 Am I correct that in -- in your research, nor in</p> <p>5 your report, did you attempt to determine whether</p> <p>6 the levels of NDMA and NDEA in the valsartan tablets</p> <p>7 at issue here, whether that level poses an increased</p> <p>8 risk of cancer?</p> <p>9 MR. NIGH: Object to form.</p> <p>10 THE WITNESS: Specifically looking at</p> <p>11 the levels, no. I made general sort of</p> <p>12 analogies based on the NDMA levels in the</p> <p>13 different manufacturers with respect to the --</p> <p>14 the sort of a dose response relations that I</p> <p>15 found from the occupational and epi studies.</p> <p>16 BY MR. FOWLER:</p> <p>17 Q I see.</p> <p>18 MR. FOWLER: By the way, Mr. Nigh, is</p> <p>19 there any reason that you're not on camera as a</p> <p>20 -- as a speaking role in this deposition?</p> <p>21 MR. NIGH: We have had many of us that</p> <p>22 haven't been on camera on speaking objections,</p> <p>23 you know, the people that are handling the</p> <p>24 depositions. So I have seen it on multiple</p> <p>25 occasions from attorneys throughout this</p>

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1 litigation. So I'm not sure why at this point
 2 you're raising this issue, almost nine hours
 3 into the deposition.
 4 MR. FOWLER: Well, you were initially
 5 yesterday, but if you're not comfortable,
 6 that's -- that's fine. I'll -- I'll leave it
 7 alone.
 8 BY MR. FOWLER:
 9 Q Dr. Etminan, let me shift gears here
 10 and go back to yesterday. I think your CV was
 11 marked as Exhibit 2. I'd like to -- to put your CV
 12 up.
 13 MR. FOWLER: I don't know, Justin, if
 14 you can do that. I think it was Number 2.
 15 BY MR. FOWLER:
 16 Q Are you with me, sir?
 17 A Yes.
 18 Q Directing your attention to the top,
 19 you see the date of May 2021. Is that the date that
 20 you revised or updated your CV?
 21 A Yes.
 22 Q And when you did that, did you review
 23 your entire CV for accuracy and any changes that
 24 needed to be made?
 25 A To the best of my ability, yes.

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1 Q And you would -- you believe
 2 everything that you've stated on your CV is true and
 3 accurate to the best of your knowledge?
 4 A Yes.
 5 Q Do you recall what changes that you
 6 made or additions in May of 2021? Was it simply
 7 publications, or was it something else?
 8 A No. It's usually just adding new
 9 publications.
 10 Q Yes, sir.
 11 Now, presently, according to your CV,
 12 you are an associate member in neurology, department
 13 of medicine; and associate member, department of
 14 anesthesiology, pharmacology and therapeutics.
 15 What -- what responsibilities, if any,
 16 do you have in the department of neurology, for
 17 example?
 18 A So as an associate member, my
 19 responsibilities are far fewer than my -- my own
 20 department, which is ophthalmology. For -- for
 21 neurology, I'm a reviewer for the journal --
 22 movement disorder and epidemiology reviewer for the
 23 journal "Movement Disorder" where the editor in
 24 chief happens to be also in the department of
 25 neurology. So that's -- that's the connection.

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1 Q And you are -- your title as associate
 2 professor in the department of ophthalmology is not
 3 because you had any education, training or
 4 experience in ophthalmology before changing to that
 5 department, correct?
 6 A Correct. So the department of
 7 ophthalmology has clinical faculty who are
 8 ophthalmologists. Then they have -- and then they
 9 have research faculty, and I'm part of the research
 10 faculty.
 11 Q Yes, sir.
 12 And -- and prior to that, you were in
 13 the department of pediatrics; is that correct?
 14 A Yes. Yes.
 15 Q And you are no more a pediatrician
 16 than you are an ophthalmologist, right?
 17 A Correct.
 18 Q You simply acquire the title when you
 19 are transferred from one department to another?
 20 A Well, the title doesn't -- I mean,
 21 title is assistant professor or associate professor,
 22 and then the department changes, right? So I'm not
 23 sure what you mean by "title."
 24 Q Okay. Well, before, you were an
 25 associate professor in the department of pediatrics

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1 at one point, the department of respiratory medicine
 2 at another point, correct?
 3 A Correct.
 4 Q But you have no medical training in
 5 either of those specialties, right?
 6 A Correct.
 7 Q And you call yourself -- or I've seen
 8 you call yourself an adjunct position in the
 9 department of pharmacology. Do you still contend
 10 that's your position?
 11 MR. NIGH: Form objection.
 12 You can answer.
 13 THE WITNESS: In the department of
 14 pharmacology -- anesthesiology, pharmacology
 15 and therapeutics, yes.
 16 BY MR. FOWLER:
 17 Q Just to be clear, my question is, do
 18 you still believe that you have an adjunct position
 19 in the department of pharmacology at UBC?
 20 A Yes.
 21 MR. NIGH: Form objection.
 22 BY MR. FOWLER:
 23 Q And why do you call it adjunct? Are
 24 you teaching classes in the department of
 25 pharmacology?

<p style="text-align: right;">Page 69</p> <p>1 A I -- I -- actually used to teach</p> <p>2 classes until last year. And I have some other</p> <p>3 collaborations with some of the faculty there, so</p> <p>4 that's why I do have the adjunct position.</p> <p>5 Q I see.</p> <p>6 Let's go to the second page of your</p> <p>7 CV, please. Sir, you indicate having received your</p> <p>8 PharmD at Idaho State University, and you note</p> <p>9 clinical pharmacology next to it. Are you with me?</p> <p>10 A Yes.</p> <p>11 Q The PharmD program at Iowa [sic] State</p> <p>12 does not have a separate program or separate degree</p> <p>13 or track for clinical pharmacology, does it?</p> <p>14 A Idaho State. No. I put clinical</p> <p>15 pharmacology because many don't really understand or</p> <p>16 know who are non-pharmacists what a PharmD entails.</p> <p>17 And so I put clinical pharmacology just to explain</p> <p>18 what the degree entails, not specifically on a</p> <p>19 specific clinical pharmacology program.</p> <p>20 Q Right. So you're not holding yourself</p> <p>21 out as having received some special PharmD degree in</p> <p>22 clinical pharmacology. Those are just the words you</p> <p>23 self-selected to describe your degree, correct?</p> <p>24 A Correct.</p> <p>25 Q And likewise -- and also, sir, you</p>	<p style="text-align: right;">Page 71</p> <p>1 Your master's, your MSC from</p> <p>2 University of Toronto, is it your contention that</p> <p>3 that was specifically in clinical epidemiology, or</p> <p>4 is that, again, your choice of words to describe it?</p> <p>5 A It was in clinical epidemiology.</p> <p>6 Q And that was the degree that was</p> <p>7 specifically conferred, sir?</p> <p>8 A I believe so.</p> <p>9 Q And is it your contention that you</p> <p>10 were in a postdoc fellowship specifically in</p> <p>11 pharmacoepidemiology at McGill as opposed to a</p> <p>12 postdoc fellow in pharmacy?</p> <p>13 A No, it was specifically</p> <p>14 pharmacoepidemiology.</p> <p>15 MR. FOWLER: You can take that down.</p> <p>16 Thank you.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q Now, sir, when you conduct research</p> <p>19 projects when you seek to determine what subject</p> <p>20 you're going to investigate, you testified yesterday</p> <p>21 that you look to various areas defined -- "emerging</p> <p>22 issues," perhaps, that you wanted to investigate.</p> <p>23 Is that a fair characterization?</p> <p>24 A Yes.</p> <p>25 Q And you mentioned media as one source</p>
<p style="text-align: right;">Page 70</p> <p>1 testified yesterday you started your PharmD degree</p> <p>2 at University of British Columbia, but then you</p> <p>3 testified that you left. You, kind of, mentioned a</p> <p>4 couple of reasons.</p> <p>5 One of them, you indicated the program</p> <p>6 was shorter at Iowa State. You would get your</p> <p>7 degree -- at Idaho State. You would get your degree</p> <p>8 faster. Is that your testimony, sir?</p> <p>9 A I don't recall exactly what I said</p> <p>10 yesterday, but I could clarify.</p> <p>11 I believe I did say that the UBC</p> <p>12 pharmacy program was clinically oriented, and I</p> <p>13 wanted to pursue a research career. So I -- I</p> <p>14 didn't see a fit there. And possibly, it was -- it</p> <p>15 was a more, perhaps, busier, if you will, stringent</p> <p>16 program that I didn't think I would really benefit</p> <p>17 from. So that's why I completed my degree at Idaho.</p> <p>18 Q And there's not another reason that</p> <p>19 you left UBC that's a nonacademic reason, sir?</p> <p>20 A No.</p> <p>21 Q And the Idaho State University degree</p> <p>22 is four years just as UBC, correct?</p> <p>23 A It was a two-year -- two years post</p> <p>24 baccalaureate program.</p> <p>25 Q I see.</p>	<p style="text-align: right;">Page 72</p> <p>1 as well as health regulatory agencies, right?</p> <p>2 A Correct.</p> <p>3 Q But you also purposefully do studies</p> <p>4 with an eye towards assisting in litigation,</p> <p>5 correct, sir?</p> <p>6 A I -- I wouldn't say that -- that's</p> <p>7 something I do systematically, no.</p> <p>8 Q Doctor, have -- have you testified</p> <p>9 that you have contacted lawyers in the course of</p> <p>10 starting a study because you believe that that was</p> <p>11 going to be useful to them in litigation?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 THE WITNESS: There could have been</p> <p>14 one occasion where I was in the process of</p> <p>15 doing the same sort of study, and a lawyer may</p> <p>16 have approached me at, sort of, the same</p> <p>17 timing.</p> <p>18 BY MR. FOWLER:</p> <p>19 Q I see. And you have done that with</p> <p>20 the Mirena IUD litigation?</p> <p>21 A Yes.</p> <p>22 Q Bear with me, sir. I apologize.</p> <p>23 And you have never contacted a drug</p> <p>24 company to offer any benefit of your study or your</p> <p>25 expertise, only plaintiff lawyers, correct?</p>

<p style="text-align: right;">Page 73</p> <p>1 MR. NIGH: Object to form.</p> <p>2 THE WITNESS: Again, I -- I am not --</p> <p>3 you're sort of portraying it as I'm contacting</p> <p>4 lawyers. The Mirena situation, as I mentioned</p> <p>5 to you, was a situation where I was starting to</p> <p>6 question because it was in the media, and I was</p> <p>7 approached, sort of, in the same time by -- by</p> <p>8 -- by a lawyer.</p> <p>9 With respect to approaching</p> <p>10 manufacturers, no, I have not. But I know that</p> <p>11 my research has been used by them in their</p> <p>12 defense.</p> <p>13 BY MR. FOWLER:</p> <p>14 Q You have never been retained by a</p> <p>15 pharmaceutical company as an expert in any matter;</p> <p>16 isn't that correct?</p> <p>17 A No. I -- probably because a lot of my</p> <p>18 studies where I show an increase in risk with a</p> <p>19 drug, you know, they -- they don't, probably, want</p> <p>20 to retain me. So that's why -- that's one of the</p> <p>21 reasons I believe I have not been retained.</p> <p>22 Q And they have never -- well, strike</p> <p>23 that.</p> <p>24 You've only been retained by counsel</p> <p>25 for plaintiff in litigations involving</p>	<p style="text-align: right;">Page 75</p> <p>1 same since 2017, sir?</p> <p>2 A Since 2017, I would say it -- I would</p> <p>3 say it may have increased.</p> <p>4 Q And other than the matter for</p> <p>5 ranitidine that you were instructed not to discuss</p> <p>6 further yesterday, do you have other pending</p> <p>7 litigation matters that you are involved in? I'm</p> <p>8 not asking what at the moment, sir.</p> <p>9 A You just want to know if I am involved</p> <p>10 in other litigation?</p> <p>11 Q Yes, sir.</p> <p>12 A Yes.</p> <p>13 Q Okay. About how many? If this is one</p> <p>14 and ranitidine is two, how many others?</p> <p>15 A I just have to think about it. I have</p> <p>16 to count them. When you say "litigation," do you</p> <p>17 mean just the -- sort of the -- the topic area or</p> <p>18 how many different perhaps groups or lawyers?</p> <p>19 Q What would be the best way for you to</p> <p>20 describe how many other topics that you are working</p> <p>21 with lawyers on presently other than the two I have</p> <p>22 mentioned?</p> <p>23 A I would say two other topics.</p> <p>24 Q Okay. Do you have any other</p> <p>25 depositions scheduled, sir?</p>
<p style="text-align: right;">Page 74</p> <p>1 pharmaceuticals; isn't that correct?</p> <p>2 A Yes.</p> <p>3 Q And you withdrew from a case where you</p> <p>4 were retained by plaintiffs' counsel, you said</p> <p>5 yesterday it was because of the science. But isn't</p> <p>6 the reason that you withdrew from Copley v. Bayer</p> <p>7 was because you weren't happy with your -- with the</p> <p>8 lawyer you were working with?</p> <p>9 A That could have been one of the</p> <p>10 reasons as well.</p> <p>11 Q Sir, do you recall testifying that as</p> <p>12 a consultant for plaintiffs in the Risperdal</p> <p>13 litigation that you were paid approximately</p> <p>14 \$200,000?</p> <p>15 A I don't -- that number, I don't recall</p> <p>16 that number. I'm not sure if that's an accurate</p> <p>17 number.</p> <p>18 Q Have you testified that your annual</p> <p>19 lawyer consulting income is 20 to \$30,000 a year, at</p> <p>20 least in 2017, sir?</p> <p>21 A That -- I may have mentioned that as</p> <p>22 an approximation, but -- but I don't really know</p> <p>23 what that \$200,000 figure is coming from.</p> <p>24 Q Have -- has your consulting with</p> <p>25 plaintiff lawyers increased, decreased or stayed the</p>	<p style="text-align: right;">Page 76</p> <p>1 A No.</p> <p>2 Q Prior to your deposition, counsel for</p> <p>3 the plaintiffs provided some documents to the</p> <p>4 defendants, and what I'd like to do is just mark</p> <p>5 that entire set of documents as an exhibit. Then</p> <p>6 there may be some that I pull out.</p> <p>7 MR. FOWLER: Can we do that, Steve?</p> <p>8 Can we mark that entire production as -- as the</p> <p>9 next exhibit?</p> <p>10 MR. HARKINS: That will be marked as</p> <p>11 Exhibit 28. It may take a moment to upload.</p> <p>12 MR. FOWLER: Thank you.</p> <p>13 THE WITNESS: Can I take a two-minute</p> <p>14 break if you don't mind?</p> <p>15 MR. FOWLER: Absolutely, Doctor.</p> <p>16 You're in charge. Off the record.</p> <p>17 THE VIDEOGRAPHER: The time is now</p> <p>18 10:12. We're going off the record.</p> <p>19 (Whereupon, a short break was taken.)</p> <p>20 (Whereupon, Exhibit 28 was marked for</p> <p>21 Identification.)</p> <p>22 THE VIDEOGRAPHER: The time is now</p> <p>23 10:15. We're back on the record.</p> <p>24 BY MR. FOWLER:</p> <p>25 Q Doctor, I would submit that Exhibit 28</p>

<p style="text-align: right;">Page 77</p> <p>1 is a composite exhibit of documents that were 2 provided by counsel for plaintiffs to the defense 3 counsel prior to your dep. 4 Did you have any role in deciding, for 5 example, which articles would be included in that 6 set of documents? 7 MR. NIGH: Form objection. 8 THE WITNESS: Yes. So I included 9 documents that weighted heavily in my report 10 and the opinion presented in my report. So all 11 the major studies that I relied on, my search 12 strategy are all included. 13 BY MR. FOWLER: 14 Q And where did you get copies of those 15 articles? 16 A I ascertained the articles through the 17 UBC library, electronic library. 18 Q Yes, sir. 19 MR. FOWLER: Let's mark as Exhibit 29 20 the search criteria documents, if I can refer 21 to those as such. Are you with me, Doctor? Do 22 you know what I mean? 23 (Whereupon, Exhibit 29 was marked for 24 Identification.) 25 THE WITNESS: Which exhibit is this?</p>	<p style="text-align: right;">Page 79</p> <p>1 was just waiting for the doctor. 2 MR. FOWLER: Okay. Because I'm not 3 seeing it. There we go. 4 BY MR. FOWLER: 5 Q Okay, sir. So let's first orient 6 ourselves to this. Can we scroll to the second 7 page? Do you see we have bladder cancer there, 8 Doctor, in the next page? 9 A Yes. 10 Q And brain -- brain tumors. 11 You're not offering any opinion that 12 NDMA at the levels contained in the valsartan pills 13 caused brain tumors, are you? 14 A No, but I -- 15 Q Let's go to the top the first page. 16 MR. NIGH: Hold on. Hold on. You 17 interrupted his answer. You gotta let him 18 finish. 19 MR. FOWLER: I'm sorry. He answered 20 no. 21 MR. NIGH: No. No. No. He was not 22 finished. He said, "No, but," and you just 23 spoke up. You gotta let him finish. 24 BY MR. FOWLER: 25 Q I'm sorry, Doctor. Go ahead.</p>
<p style="text-align: right;">Page 78</p> <p>1 MR. FOWLER: It will be 29. Bear with 2 me. It's going to come up. 3 BY MR. FOWLER: 4 Q And as it's posting, Doctor, you would 5 agree that you attempted to set forth in the 6 documents we're going to look at, your quote/unquote 7 search methodology for selecting documents to review 8 for your report; is that a fair statement? 9 A Yes. 10 Q And other than the searches that we're 11 going to look at here that are described for the 12 various cancers, was there any other medical 13 database that you reviewed or other research you did 14 to select articles other than what was the product 15 of this search criteria that we're going to look at 16 here on Exhibit 29? 17 A So as I mention in my report, I also 18 looked at -- I used Google Scholar using the same 19 terminologies. And I found pertinent articles 20 through reviewing the articles that I -- I had found 21 in case they were not listed in my search. 22 MR. FOWLER: How are we doing on 23 Exhibit 29? 24 THE WITNESS: I'm looking at it. 25 THE VIDEOGRAPHER: Yes, it's up. I</p>	<p style="text-align: right;">Page 80</p> <p>1 A Because I did a systematic review of 2 the literature of NDMA with all types of cancer, I 3 included all types of cancer in my original search. 4 And then I -- and after I looked at the evidence and 5 synthesized the evidence, then I chose, depending on 6 the amount of data that I had, which cancers to 7 include and which not to include. 8 So, again, to be thorough and 9 systematic, I did include all types of cancers in my 10 search. But depending on the type of data and 11 whether the data met my inclusion criteria, then I 12 went ahead and mentioned in the report or included 13 data for that in the report. 14 Q I see. 15 MR. FOWLER: Let's go to Page 1 of 16 Exhibit 19 -- I mean, Exhibit 29. Now -- thank 17 you. 18 BY MR. FOWLER: 19 Q What we're looking at here, Doctor, 20 and -- is this a document that you created, or is 21 it -- is it a printout, if you will, from your 22 search engine? 23 A It's a printout. It's an electronic 24 output of the search that I did. 25 Q Okay. Thank you. And what does the</p>

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<p>1 EXP mean?</p> <p>2 A It means expanded.</p> <p>3 Q And what -- what you do you understand</p> <p>4 expanded to mean?</p> <p>5 A So that -- that -- basically, it looks</p> <p>6 at all terminologies that would be related to</p> <p>7 nitrites, all different chemical -- chemicals that</p> <p>8 may be tagged in the database as nitrites just to</p> <p>9 be -- to make sure that nothing is missed.</p> <p>10 Q So do I understand, in Line 1, that</p> <p>11 your search would have included not only NDMA, but</p> <p>12 any nitrosamines?</p> <p>13 A Yes, because NDMA by itself does not</p> <p>14 have --</p> <p>15 THE COURT REPORTER: I'm sorry. Does</p> <p>16 not have a what?</p> <p>17 THE WITNESS: They don't have a MeSH</p> <p>18 M-e-S-H, which stands for medical subject</p> <p>19 heading. I believe it's -- I believe it stands</p> <p>20 for medical subject heading.</p> <p>21 Anyway, it's the -- it's the key</p> <p>22 medical terminologies that are tagged by the</p> <p>23 National Library of Medicine, PubMed. So NDMA</p> <p>24 does not have a specific tag, but it's tagged</p> <p>25 under "nitrosamines."</p>	<p>1 BY MR. FOWLER:</p> <p>2 Q Correct, Doctor?</p> <p>3 A Yes.</p> <p>4 Q And same question here for the brain</p> <p>5 tumors, it's your contention that you reviewed 64</p> <p>6 articles looking for NDMA or NDEA?</p> <p>7 A Yes.</p> <p>8 MR. FOWLER: Next -- next page.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q And for breast cancer, is it your</p> <p>11 contention you reviewed the 115 articles that are on</p> <p>12 line 16 looking for NDMA and NDEA?</p> <p>13 A Yes.</p> <p>14 MR. FOWLER: Next page.</p> <p>15 BY MR. FOWLER:</p> <p>16 Q You contend there are 130 articles</p> <p>17 that you looked through here?</p> <p>18 A Yes.</p> <p>19 Q And you did this all -- let me ask it</p> <p>20 differently.</p> <p>21 Did you use any kind of electronic</p> <p>22 search method as you're reviewing these several</p> <p>23 hundred articles, sir?</p> <p>24 A No. I just went through them, read</p> <p>25 the title of the article, read the abstract and then</p>
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<p>1 So, again, to be ensuring that I'm not</p> <p>2 missing anything, I started the search with</p> <p>3 nitrosamine, which is the bigger umbrella term.</p> <p>4 But then I restricted at the end my inclusion</p> <p>5 for studies that -- specifically with NDMA.</p> <p>6 MR. FOWLER: Let's go to the next</p> <p>7 page.</p> <p>8 BY MR. FOWLER:</p> <p>9 Q So for bladder cancer, sir, as I read</p> <p>10 this, again, your 120 articles that come out of --</p> <p>11 at Line 8, include anything to do with nitrosamines</p> <p>12 or nitrites or NDMA, right?</p> <p>13 A Right. So then what I -- what I did</p> <p>14 was, go through the 120 articles, which would have</p> <p>15 been animal studies where they could have looked at</p> <p>16 NDMA, NDEA or other nitrosamines. But then I only</p> <p>17 selected those that met my inclusion criteria, which</p> <p>18 is specifically looking at nitrosamines, NDMA or</p> <p>19 NDEA.</p> <p>20 MR. FOWLER: Next page, please.</p> <p>21 BY MR. FOWLER:</p> <p>22 Q So there are 120 articles you said you</p> <p>23 reviewed there, correct?</p> <p>24 MR. NIGH: Form objection.</p> <p>25</p>	<p>1 decided whether they would meet my inclusion</p> <p>2 criteria or not.</p> <p>3 Q And with regard to your inclusion</p> <p>4 criteria, you mentioned yesterday that it was</p> <p>5 important to you that the -- if NDMA is mentioned,</p> <p>6 that it be quantified when it's mentioned. Is that</p> <p>7 an accurate statement of your testimony yesterday,</p> <p>8 sir?</p> <p>9 A Yes.</p> <p>10 Q It was important to you that there be</p> <p>11 a measure of NDMA, not just a broad reference to</p> <p>12 NDMA. Does that make sense to you?</p> <p>13 A Yes.</p> <p>14 Q Okay.</p> <p>15 MR. FOWLER: Next page, please.</p> <p>16 BY MR. FOWLER:</p> <p>17 Q And Doctor, of course, you -- you</p> <p>18 billed for all your time reviewing these 6, 7, 800</p> <p>19 articles, didn't you?</p> <p>20 A It was part of my work that I bill for</p> <p>21 it, yes.</p> <p>22 Q And you would have reviewed all of</p> <p>23 these before you put pen to paper for your report?</p> <p>24 A I'm not sure. I mean, either before</p> <p>25 or maybe during the time I was writing, perhaps, say</p>

<p style="text-align: right;">Page 85</p> <p>1 the introduction of the report, but definitely prior 2 to the time where I sort of formed -- you know, 3 formulated my opinion on the different types of 4 cancer. 5 Q And is it your testimony that you 6 can't go to PubMed and put in "NDMA" and "cancer," 7 that it's not going to give you any results? Is 8 that what you're saying? 9 MR. NIGH: Form objection. 10 THE WITNESS: It will give the 11 results, but -- but it may not give you 12 accurate results. There could be studies that 13 may not be included in that search strategy. 14 BY MR. FOWLER: 15 Q So you didn't do it? 16 MR. NIGH: Object to form. 17 THE WITNESS: No, because, again, I 18 wanted to be more thorough and do a -- do a 19 more systematic approach. 20 BY MR. FOWLER: 21 Q Okay. Okay. And when -- let's say 22 here in esophageal cancer, in those 19 articles, if 23 you came across one or two that looked good to you, 24 would you stop there, or would you look through all 25 19?</p>	<p style="text-align: right;">Page 87</p> <p>1 Through what? You would get it -- you would 2 get it through what? 3 THE WITNESS: Interlibrary loan 4 service. 5 BY MR. FOWLER: 6 Q And, Doctor, for each article that you 7 contend met your inclusion criteria -- let's stick 8 with esophageal cancer here -- did you cite all of 9 those articles in your report? 10 A No, I only cited, again, the articles 11 that met my inclusion criteria. 12 Q Well, that was my question, sir. 13 Let's say esophageal cancer, there 14 were 9 out of the 19 that met your inclusion 15 criteria. Would you have cited all 9, or did you 16 have another cut as to what you were going to cite? 17 A No. If -- if they met the inclusion 18 criteria, I mentioned them. 19 THE COURT REPORTER: Counsel, can we 20 go off the record for one second? 21 MR. FOWLER: Certainly. 22 THE VIDEOGRAPHER: The time is now 23 10:29. We're going off the record. 24 (Whereupon, a short break was taken.) 25 THE VIDEOGRAPHER: The time is now</p>
<p style="text-align: right;">Page 86</p> <p>1 A I'm not sure what you mean by "looked 2 good." So I went through the 19, and all from -- 3 from the denominator of the 19 articles, whichever 4 met my inclusion criteria was reviewed. 5 Q Okay. And did you electronically 6 slide those over to some file on your computer? Did 7 you print them? What did you do with it once you 8 identified an article? 9 A I -- I tried to look at the -- or find 10 the PDF versions so I could read them, and then I 11 would -- I saved them in files under different, you 12 know, sort of cancers. 13 Q I see. 14 And what if it -- let me start that 15 again. 16 Did you have to purchase any of the 17 articles that came up? 18 A No. 19 Q If -- if, for example, your search in 20 PubMed came up with an article that required 21 purchase, did you just move on to the next article? 22 A No. I would not leave important data 23 because it could not be purchased. I would try to 24 get it through -- 25 THE COURT REPORTER: Through what?</p>	<p style="text-align: right;">Page 88</p> <p>1 10:29. We're back on the record. 2 BY MR. FOWLER: 3 Q Doctor, do you recall yesterday when 4 we were talking about your report and that Table 1 5 on Page 15, you testified that you determined the -- 6 the level of an unmeasured confounder that would be 7 necessary to change the relative risk reported for 8 an individual cancer? Did I get that right? 9 A Yes. 10 Q And you used this E-value methodology 11 that you referred to in your report, right? 12 A Yes. 13 Q And with regard to the E-value 14 methodology, do I recall your testimony correctly 15 that the E-valued methodology can't be applied if 16 there's more than one unmeasured confounder? 17 A Yes. 18 Q And so if -- in Table 1, if there was 19 more than one unmeasured confounder amongst, let's 20 say, the Hidajat study that you pulled from, this 21 table would be moot, correct? 22 MR. NIGH: Form objection. 23 THE WITNESS: If there was a true 24 unmeasured confounder, and we talked a lot 25 about this topic yesterday, then this -- again,</p>

<p style="text-align: right;">Page 89</p> <p>1 this method is only designed to look at one.</p> <p>2 BY MR. FOWLER:</p> <p>3 Q Yes, sir. And you would consider that</p> <p>4 a limitation of the E-value methodology, sir?</p> <p>5 A Yes.</p> <p>6 Q Okay. Are you aware of other</p> <p>7 limitations to using an E-value methodology?</p> <p>8 A The E-value methodology, like any</p> <p>9 epidemiologic tool, has -- or carries a number of</p> <p>10 assumptions. So, yes, it does have some assumptions</p> <p>11 built into it. But I think that overall, it is a</p> <p>12 widely accepted methodology.</p> <p>13 Q Okay. Thank you. I think that was an</p> <p>14 answer to a different question. Let me ask my</p> <p>15 question. Listen carefully, please.</p> <p>16 Are you aware of any limitations to</p> <p>17 using the E-value methodology, yes or no, sir?</p> <p>18 MR. NIGH: Form objection.</p> <p>19 THE WITNESS: What do you mean by --</p> <p>20 MR. NIGH: Hold on. Hold on. Form</p> <p>21 objection and argumentative.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: Can you -- can you</p> <p>24 clarify what you mean by "limitations"? One</p> <p>25 limitation we just agreed on is that it only</p>	<p style="text-align: right;">Page 91</p> <p>1 BY MR. FOWLER:</p> <p>2 Q Are you aware of any articles critical</p> <p>3 of applying the E-value methodology?</p> <p>4 A There have been articles talking about</p> <p>5 its limitations, yes.</p> <p>6 Q And did you review those prior to</p> <p>7 applying the E-value methodology here to make sure</p> <p>8 it was a good fit?</p> <p>9 A No. Because again, it is an accepted</p> <p>10 methodology used despite -- I mean, limitation is</p> <p>11 a -- is a very complex term. There could be</p> <p>12 limitations to a methodology, but it's still -- the</p> <p>13 limitations do not outweigh its strengths. And then</p> <p>14 there are limitations where you should not really</p> <p>15 use a specific approach.</p> <p>16 In this case, there are limitations,</p> <p>17 but I think that if -- the strengths of the</p> <p>18 methodology outweighs its limitations. And that's</p> <p>19 why it's widely used as one way to assimilate what</p> <p>20 would happen to the effect size in the absence of an</p> <p>21 unmeasured confounder.</p> <p>22 Q And, Doctor, for each of the cancers</p> <p>23 in your Table 1 where you drew the -- the -- let me</p> <p>24 start that again.</p> <p>25 For each of the cancers listed in</p>
<p style="text-align: right;">Page 90</p> <p>1 looks at -- it can only quantify one unmeasured</p> <p>2 confounder.</p> <p>3 BY MR. FOWLER:</p> <p>4 Q Okay.</p> <p>5 A What -- what -- what other</p> <p>6 limitations? Can you -- if you could just elaborate</p> <p>7 on that wording.</p> <p>8 Q Well, that's exactly what I'm asking</p> <p>9 you, sir.</p> <p>10 You expressed limitations about all</p> <p>11 sorts of studies yesterday, and I'm asking about</p> <p>12 this methodology. You know what the term</p> <p>13 "limitations" means, right, sir?</p> <p>14 A Yes.</p> <p>15 Q Okay. What other limitations -- and</p> <p>16 if you don't know, that's fine. Are there other</p> <p>17 limitations of the E-value methodology?</p> <p>18 MR. NIGH: Form objection.</p> <p>19 THE WITNESS: Again, one limitation is</p> <p>20 what we spoke about. The other limitation is</p> <p>21 that the unmeasured confounder has to satisfy a</p> <p>22 couple of other sort of criteria for the -- for</p> <p>23 the E-value to work, but that's just like any</p> <p>24 statistical model that is -- are based on</p> <p>25 assumptions.</p>	<p style="text-align: right;">Page 92</p> <p>1 Table 1 where you have attempted to apply the</p> <p>2 E-value methodology, if there is an unmeasured</p> <p>3 confounder for any one or all of those cancers, your</p> <p>4 conclusions from Table 1 would be null and void;</p> <p>5 they would be moot, correct?</p> <p>6 A No. That's not what Table 1 means.</p> <p>7 Q Table 1, the magnitude of hazard ratio</p> <p>8 on your right-hand column is derived using the</p> <p>9 E-value methodology, correct?</p> <p>10 A It's the magnitude of the hazard ratio</p> <p>11 of the unmeasured confounder necessary to make the</p> <p>12 hazard ratio on the left null, so for the first</p> <p>13 cancer, for it to go from 1.72 to 1.0.</p> <p>14 Q Yes, sir. Thank you.</p> <p>15 And if that stomach cancer there is a</p> <p>16 second unmeasured confounder that you would not be</p> <p>17 able to calculate -- strike that -- you would not be</p> <p>18 able to apply the E-value methodology. I thought we</p> <p>19 established that; am I right?</p> <p>20 A Correct.</p> <p>21 MR. NIGH: Form objection.</p> <p>22 BY MR. FOWLER:</p> <p>23 Q Okay.</p> <p>24 THE COURT REPORTER: Counsel, I'm</p> <p>25 sorry. Can we just go off the record for one</p>

<p style="text-align: right;">Page 93</p> <p>1 more second?</p> <p>2 MR. FOWLER: Sure.</p> <p>3 THE VIDEOGRAPHER: The time is now</p> <p>4 10:36. This ends Media Unit Number 2. We're</p> <p>5 going off the record.</p> <p>6 (Whereupon, a short break was taken.)</p> <p>7 THE VIDEOGRAPHER: The time is now</p> <p>8 10:37. This begins Media Unit Number 3. We're</p> <p>9 back on the record.</p> <p>10 BY MR. FOWLER:</p> <p>11 Q Doctor, from the Hidajat study on the</p> <p>12 rubber workers, you agree that they were exposed to</p> <p>13 multiple carcinogens, correct?</p> <p>14 MR. NIGH: Object to form. I think</p> <p>15 that's the 21st time that question has been</p> <p>16 asked.</p> <p>17 MR. FOWLER: Well, it was just a</p> <p>18 foundation because I was shifting gears, sir.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q Right, Doctor?</p> <p>21 A Correct.</p> <p>22 Q And you have not and cannot draw any</p> <p>23 conclusion that any of the workers who expired in</p> <p>24 that study died from NDMA cancer, NDMA-induced</p> <p>25 cancer, correct?</p>	<p style="text-align: right;">Page 95</p> <p>1 like to clarify that endogenous -- endogenous NDMA</p> <p>2 or nitrosamines or NDMA, nitroso compounds in</p> <p>3 general, I mean, they are already in the body. But</p> <p>4 they have -- they have been -- they got into the</p> <p>5 body from the outside, from the environment, from</p> <p>6 our food.</p> <p>7 So now that I think about it again, I</p> <p>8 believe both exogenous and endogenous may take time</p> <p>9 for -- you know, for their effect to take place with</p> <p>10 respect to cancer.</p> <p>11 I think the reason I said what I said</p> <p>12 yesterday is it was in reference to the Jakszyn</p> <p>13 study because the Jakszyn study had data on</p> <p>14 endogenous nitrosamines, which means that they had</p> <p>15 already been there and measured in that population.</p> <p>16 But they had to get there somehow in</p> <p>17 the body, and that's probably through, again,</p> <p>18 outside. So a lot of endogenous NDMA could</p> <p>19 initially be exogenous, and it's just a matter of</p> <p>20 when you're measuring, you know. When you're</p> <p>21 measuring NDMA, you're measuring somebody's blood,</p> <p>22 and there is NDMA in there, that would be</p> <p>23 endogenous. But they have to be taking it from the</p> <p>24 outside to -- for that NDMA to get into the body.</p> <p>25 So I'm not sure if I answered your</p>
<p style="text-align: right;">Page 94</p> <p>1 A Can you repeat the question, please?</p> <p>2 Q You cannot tell -- and the authors of</p> <p>3 this study made no -- reached no conclusion that any</p> <p>4 of the workers who died during this study period</p> <p>5 died as a result of NDMA-induced cancer; isn't that</p> <p>6 correct?</p> <p>7 A Well, the study actually showed</p> <p>8 elevated risks of death secondary to high NDMA use</p> <p>9 versus low NDMA use in the different types of</p> <p>10 cancer. That's what the study actually set out to</p> <p>11 do. I'm -- I'm missing your question. I'm sorry.</p> <p>12 Q Okay. I'll just withdraw that and</p> <p>13 move on.</p> <p>14 Sir, you testified yesterday that the</p> <p>15 mechanism of cancer with exogenous exposure may take</p> <p>16 longer follow up than for endogenous exposure. Do</p> <p>17 you recall that testimony?</p> <p>18 A I do. If I could clarify.</p> <p>19 Q I really -- I only had that one</p> <p>20 question, if you recall testifying.</p> <p>21 And so my follow-up to that is, you</p> <p>22 further testified that you believe it takes longer</p> <p>23 because you have to take it longer. It has to be</p> <p>24 digested and absorbed. Do you recall saying that?</p> <p>25 A Well, now that I think about it, I'd</p>	<p style="text-align: right;">Page 96</p> <p>1 question, but I just wanted to clarify on endogenous</p> <p>2 versus exogenous.</p> <p>3 Q Thank you, Doctor.</p> <p>4 And if I understand what you just</p> <p>5 said, you believe that -- that endogenous levels of</p> <p>6 NDMA at some point started from the outside? Is</p> <p>7 that what you're saying?</p> <p>8 A I think so, because as we've</p> <p>9 discussed, they -- NDMA is in the environment, and</p> <p>10 it gets into our body eventually. So I'm not aware</p> <p>11 of any mechanisms that the body itself creates</p> <p>12 endogenous NDMA. It has to be brought into our body</p> <p>13 from -- exogenously, if you will.</p> <p>14 Q You're not aware because you're not a</p> <p>15 toxicologist, correct?</p> <p>16 A No.</p> <p>17 Q This is completely outside your field</p> <p>18 of education, training or experience to be</p> <p>19 commenting on endogenous NDMA, correct, sir?</p> <p>20 MR. NIGH: Object to form. He's been</p> <p>21 asked numerous questions about this.</p> <p>22 You can -- you can answer.</p> <p>23 THE WITNESS: I -- I -- again, I was</p> <p>24 asked about endogenous NDMA with respect -- in</p> <p>25 an epidemiological studies context. I did not</p>

<p style="text-align: right;">Page 97</p> <p>1 opine, nor did I -- was I asked, I believe, to 2 opine about, you know, toxicologic -- 3 toxicological aspects of endogenous NDMA. It 4 was just in the context of that one study -- 5 study that we discussed yesterday. 6 BY MR. FOWLER: 7 Q Okay. Thank you. 8 And, Doctor, am I correct that you are 9 unaware of the mechanism by which NDMA can be a 10 carcinogenic substance in animals, for example? 11 A Well, from the literature that I have 12 read and I have included in my report, it's through 13 genotoxic mechanisms and potentially through other 14 mechanisms that would qualify as a promoter for 15 cancer. 16 Q You are not -- you have never 17 published on quote/unquote cancer promoters, have 18 you, sir? 19 THE COURT REPORTER: Cancer what? 20 MR. FOWLER: Promoters. 21 BY MR. FOWLER: 22 Q Right? 23 A No, that's not my field. What I 24 was -- what I was trying to say is that for the 25 biological plausibility section of my report and my</p>	<p style="text-align: right;">Page 99</p> <p>1 you're asking me. That's not my field, and I 2 did not look at that. 3 BY MR. FOWLER: 4 Q Does -- does exposure to a chemical 5 that -- that is being studied, does exposure affect 6 the biologic plausibility in any attempt to evaluate 7 the biologic plausibility, sir? 8 MR. NIGH: Form objection. 9 THE WITNESS: Can you clarify? 10 BY MR. FOWLER: 11 Q Sure. Does the method of exposure 12 affect the analysis of biologic plausibility when 13 assessing if exposure can lead to cancer? 14 MR. NIGH: Form objection. 15 THE WITNESS: Yes, it could. 16 BY MR. FOWLER: 17 Q Doctor, the Hidajat study used a 18 sub-distribution hazard analysis; is that your 19 recollection? 20 A That's right. 21 Q And given that it was over the course 22 of 49 years of observation, the 94.1 percent of the 23 study had died, would you agree it's very difficult 24 to determine cause of death? 25 A I disagree because this was one of the</p>
<p style="text-align: right;">Page 98</p> <p>1 readings, I have reviewed some basic science cancer 2 studies to form my opinion about the mechanism of 3 NDMA cancer. 4 Q And you do not have an opinion whether 5 any of the NDMA or NDEA contained in valsartan 6 products ever leaves the liver, correct? 7 MR. NIGH: Form objection. 8 THE WITNESS: I cannot -- I don't have 9 an opinion on that. 10 BY MR. FOWLER: 11 Q And if it doesn't leave -- did you 12 consider what body systems -- what tissue systems 13 NDMA that is ingested in -- with an oral -- orally 14 ingested in tablet form, did you make any attempt to 15 consider what parts of the body that oral ingestion 16 may reach at the level of exposure in the pill? 17 A I believe that's a -- 18 MR. NIGH: Hold on. Hold on. Hold 19 on. Hold on. 20 Are you done with the question? 21 MR. FOWLER: I am. 22 MR. NIGH: Okay. Form objection. 23 You can answer, Doctor. 24 THE WITNESS: I believe that's a more 25 of a basic pharmacology toxicology question</p>	<p style="text-align: right;">Page 100</p> <p>1 few papers that actually -- what the 2 sub-distribution hazard that you explained does is 3 actually controlled -- it calculates the hazard of 4 death. It controls the hazard of death due to 5 cancer from death due to other causes. And this was 6 rightfully done -- because of the very long follow 7 up, it's likely that these men could die of other 8 causes. 9 And if you don't take that into 10 account, you may actually see a protective effect 11 from any exposure, because people are not surviving 12 long enough to get cancer. And so the 13 sub-distribution hazard -- it's called 14 sub-distribution hazard because it comes from a sort 15 of a -- I don't want to say different, but a more 16 sophisticated model that takes into account death 17 due to other causes. 18 Q Do you know how to calculate a 19 sub-distribution hazard ratio? 20 A I'm familiar with the methodology, and 21 the modeling that -- they have the equation in their 22 paper actually. 23 Q But you've never done it? 24 A I don't think I have done it -- 25 MR. NIGH: Hold on. Hold on.</p>

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<p>1 Form objection. I can't tell, "you've 2 never done it," calculated whenever or from 3 that study. Form objection. 4 MR. FOWLER: Thank you for clarifying, 5 Counsel. 6 BY MR. FOWLER: 7 Q Dr. Etminan, you have never, yourself, 8 made any such calculation of a sub-distribution 9 hazard ratio at any time, correct? 10 A No, because I haven't done studies 11 that have such a long follow up. So I have not done 12 it myself, but I'm familiar with the methodology. 13 Q Okay. Sir, yesterday, we talked -- or 14 you talked a good bit about the relative risk 15 calculations and your opinions with regard to when 16 there is a wide confidence interval. Do you recall 17 those -- that testimony? 18 A Yes. 19 Q And you -- you said that it was a wide 20 confidence interval because of a small sample size? 21 Is that -- is that what you believe? 22 A Well, sometimes it is a sample size, 23 but it's actually more a function of number of cases 24 or cancer cases, which sometimes can be a function 25 of sample size, sometimes not. So if I want to be</p>	<p>1 number of events are sort of directly proportional. 2 But there are situations such as cancer where you 3 have a large sample size, but you still have a small 4 number of events. So what affects the precision of 5 confidence interval is mostly -- it can be a sample 6 size issue, but it's mostly directly related to the 7 number of events or cases. 8 Q Doctor, you mentioned several times 9 yesterday that the P value, according to the ASA, 10 has -- has lost importance; is that a fair 11 characterization? 12 A Well, it's still being used and 13 accepted by many journals, but what I -- I believe I 14 said was that the ASA has warned on the 15 interpretation of what the P value is and what it is 16 not. 17 Q Yes, sir. And the P value is simply 18 the probability that results such as those actually 19 observed in the study could arise under the null 20 hypothesis? That's what a P value is, correct? 21 A Yes. 22 Q And what is the null hypothesis in the 23 Hidajat study, Doctor? 24 MR. NIGH: Form objection. 25 THE WITNESS: The null hypothesis --</p>
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<p>1 more precise, I would say that the width of the 2 confidence interval is -- is one of the -- one of 3 the variables that affects the precision or the 4 width of the confidence interval or the number of 5 events or cases, which -- which could be related to 6 sample size. 7 Q And you agree, Doctor, that high 8 variability can also affect the confidence interval? 9 A That is also one of the other 10 parameters that can affect the confidence interval, 11 yes. 12 Q And, Doctor, when you're talking about 13 sample size, let me just give you a hypothetical. 14 If there were 5,000 patients in a -- in a cohort 15 study and somebody is studying the number of 16 pancreatic cancers, for example, let's say there's 17 14, do you -- is it your contention that the 14 is 18 the sample size or the 5,000 cohort members? 19 A Again, to be more precise, in many 20 cases, sample size is a function of the number of 21 cases as well. So I mean, usually if you have a 22 larger sample size for many conditions, let's say, 23 heart attacks, the more people you follow up, the 24 more people are going to have heart attacks. 25 So in this situation, sample size and</p>	<p>1 hypothesis would be that there is no risk of 2 NDMA with cancer deaths. 3 BY MR. FOWLER: 4 Q Did you operate under a null 5 hypothesis in your research and report drafting in 6 this case, sir? 7 MR. NIGH: Form objection. 8 THE WITNESS: No, because null 9 hypotheses are done when you actually want to 10 do an -- a true experiment. When you're 11 looking at observational studies you don't -- 12 you don't have a -- I mean, you don't start 13 with a null hypothesis. You -- you would form 14 a hypothesis, but null hypotheses are mostly 15 related to when you're designing your 16 randomized trial and you want to calculate your 17 sample size. And you have -- 18 THE COURT REPORTER: I'm sorry, what? 19 I'm sorry. Can you repeat the end of your 20 answer? 21 THE WITNESS: What part of it did you 22 want me to repeat? 23 THE COURT REPORTER: The hypotheses 24 are mostly related to designing your randomized 25 trial and you want to calculate your sample</p>

<p style="text-align: right;">Page 105</p> <p>1 size. And you have...</p> <p>2 THE WITNESS: Yeah. So a null</p> <p>3 hypothesis is mainly used in a true -- in a</p> <p>4 randomized trial or a true experiment. When</p> <p>5 you want to calculate your power of the study,</p> <p>6 the null hypothesis is important. But for</p> <p>7 observational studies where I'm reviewing</p> <p>8 literature on a specific topic, I don't really</p> <p>9 see why a null hypothesis would be beneficial.</p> <p>10 BY MR. FOWLER:</p> <p>11 Q Doctor, when there are studies that</p> <p>12 are based on hospitalized patients, you agree that</p> <p>13 there is a bias to the -- the self-reporting from</p> <p>14 those patients? Do you understand the question?</p> <p>15 MR. NIGH: Form objection.</p> <p>16 THE WITNESS: I understand your</p> <p>17 question, but you have to be very specific,</p> <p>18 because self -- I mean, if it's a</p> <p>19 hospital-based study and both cases and</p> <p>20 controls are in the hospital, then you wouldn't</p> <p>21 have a self-reporting limitation.</p> <p>22 So it -- it's -- you have to have the</p> <p>23 very specifics of the study, and then you have</p> <p>24 to show exactly where a limitation of bias</p> <p>25 would affect the outcome. I mean, I don't want</p>	<p style="text-align: right;">Page 107</p> <p>1 Steve, can you load that up?</p> <p>2 (Whereupon, Exhibit 30 was marked for</p> <p>3 Identification.)</p> <p>4 THE WITNESS: Do you mind if I take a</p> <p>5 break after your question with the article?</p> <p>6 MR. FOWLER: Yes, this will be -- my</p> <p>7 last series of questions will be on this</p> <p>8 article and I'm done, sir. Can you make it</p> <p>9 10 minutes?</p> <p>10 THE WITNESS: Absolutely.</p> <p>11 MR. FOWLER: Thank you.</p> <p>12 MR. HARKINS: Introduced as</p> <p>13 Exhibit 30, if we can screen share.</p> <p>14 THE WITNESS: Let me just -- I'm</p> <p>15 having trouble.</p> <p>16 BY MR. FOWLER:</p> <p>17 Q There it is. Can you see that now?</p> <p>18 A Yes.</p> <p>19 Q Okay. Thank you. Do you recognize --</p> <p>20 have you seen this article before, Doctor?</p> <p>21 A I may have. I'm not sure.</p> <p>22 Q Do you agree or disagree that when</p> <p>23 doing an analysis using the Bradford Hill criteria,</p> <p>24 that it is appropriate to look to scientific</p> <p>25 articles in addition to epidemiologic articles when</p>
<p style="text-align: right;">Page 106</p> <p>1 to make generalizations on a hospital-based</p> <p>2 study.</p> <p>3 BY MR. FOWLER:</p> <p>4 Q Sure. Let me try it this way: For a</p> <p>5 lung cancer patient who's being presented with a</p> <p>6 survey to complete which may help them understand</p> <p>7 the cause of their lung cancer, do you believe that</p> <p>8 that creates a reporting bias from the patient?</p> <p>9 MR. NIGH: Form objection.</p> <p>10 THE WITNESS: The reporting bias would</p> <p>11 only occur if the patient also believed that</p> <p>12 the -- and these questionnaires are very long.</p> <p>13 It's not about, you know, did you take this or</p> <p>14 that. They -- they covered a whole host of</p> <p>15 different items. So unless a patient knows</p> <p>16 that a specific item is linked to the -- to</p> <p>17 their lung cancer, then no, I won't -- I</p> <p>18 wouldn't see any sort of a differential bias in</p> <p>19 that situation in terms of the cases and many</p> <p>20 controls.</p> <p>21 BY MR. FOWLER:</p> <p>22 Q Okay.</p> <p>23 MR. FOWLER: I'm going to mark</p> <p>24 Exhibit 30. It's an article applying the</p> <p>25 Bradford Hill criteria in the 21st century.</p>	<p style="text-align: right;">Page 108</p> <p>1 assessing any of these criteria?</p> <p>2 A What do you mean -- what do you mean</p> <p>3 between scientific article versus epidemiological</p> <p>4 articles?</p> <p>5 Q Fair point, sir.</p> <p>6 Do you agree that studies -- molecular</p> <p>7 studies, toxicology studies are appropriate to</p> <p>8 consider along with epidemiology studies when</p> <p>9 analyzing something under the Bradford Hill</p> <p>10 criteria?</p> <p>11 MR. NIGH: Form objection.</p> <p>12 THE WITNESS: I believe it depends on</p> <p>13 the question you're trying to ask. If your</p> <p>14 question is a general causation question and</p> <p>15 part of the Bradford Hill criteria requires a</p> <p>16 biologic plausibility, which usually requires a</p> <p>17 sort of mechanistic explanation, from animal</p> <p>18 studies. Then I don't think one would need --</p> <p>19 for this specific question, need to go any</p> <p>20 further examining, you know, other than that</p> <p>21 mechanistic part of the Bradford Hill that</p> <p>22 requires some evidence of a mechanism from</p> <p>23 animal studies.</p> <p>24 Beyond that, I don't think this</p> <p>25 question warrants further review of, you know,</p>

<p style="text-align: right;">Page 109</p> <p>1 complicated toxicological studies because, 2 again, it -- the question doesn't really mean 3 that. The question is on general causation. 4 So I would -- I would maybe shorten my answer, 5 if you will. It depends on the question. 6 For the question that I answered, I 7 don't believe that those types of studies were 8 necessary. 9 BY MR. FOWLER: 10 Q Thank you. 11 Let me direct your attention to 12 criteria five, biologic gradient. 13 MR. FOWLER: I think it's on like the 14 fifth or sixth page, please. There are no page 15 numbers on mine. 16 BY MR. FOWLER: 17 Q Okay, sir. Do you see that Hill, 18 referring to Sir Bradford Hill, wrote that, "If the 19 dose response is seen, it is more likely that an 20 association is causal." 21 Do you see that, sir? 22 A Yes. 23 Q And if you look about five lines down 24 you see, "However, Hill acknowledged that the more 25 complex dose-response relationships may exist, and</p>	<p style="text-align: right;">Page 111</p> <p>1 levels of exposure for your analysis here would be 2 important? 3 MR. NIGH: Form objection. 4 THE WITNESS: Again, these are not 5 from Bradford Hill himself. I believe these 6 are the opinions of the authors, correct? 7 BY MR. FOWLER: 8 Q I'm asking if you agree with that -- 9 that statement, sir. 10 A Well, I want to -- I mean, I think 11 it's important to sort of establish that these 12 are -- what we have here on this screen and I'm 13 reading, are the opinions of the authors of this 14 paper. 15 MR. NIGH: Doctor, you have a right -- 16 you have a right to look at this document. You 17 can upload it, remember, and look at it. 18 That's why it's put into chat. 19 THE WITNESS: Okay. 20 BY MR. FOWLER: 21 Q My question, Doctor, just so you keep 22 it top of mind -- of course, you can look at 23 whatever you like. 24 Do you agree that it would have been 25 important for forming your opinions in this case to</p>
<p style="text-align: right;">Page 110</p> <p>1 modern studies have confirmed that a monotonic dose 2 response curve is an overly simplistic 3 representation of most causal relationships." 4 Do you agree with that, sir? 5 MR. NIGH: Form objection. Agree that 6 that's what it says or agree with that 7 statement? 8 MR. FOWLER: Thank you. 9 BY MR. FOWLER: 10 Q Do you agree with that statement? 11 A Again, I think Hill is presenting a 12 very general idea, and I -- it could be true for 13 some instances and perhaps not for others. 14 Q Do you believe that -- strike that. 15 Let me just look a little bit further 16 down. 17 You see after Footnote 9, "Integration 18 of advanced statistical capabilities, data modeling 19 techniques and knowledge from understanding of 20 biomolecular interactions have resulted in the 21 descriptions of more defined dose response curves 22 capable of showing molecular effects at very low 23 levels of exposure." 24 Do you agree that that -- that 25 understanding the molecular effects at very low</p>	<p style="text-align: right;">Page 112</p> <p>1 understand the molecular effects at very low level 2 of exposure to NDMA and NDEA? 3 MR. NIGH: Form objection. 4 THE WITNESS: No. I don't agree 5 because, again, I was looking at a general 6 causation question of exposure of NDMA over a 7 long period. You know, it could have been 8 three years, five years, up to 40 years. That 9 was my question. 10 And what these authors are -- are, I 11 believe, arguing, does not -- does not talk 12 about any specific type of question, does not 13 talk about the -- you know, the type of 14 exposure, the -- the risk of cancer, the type 15 of risk of cancer or the -- or the follow-up 16 involved. 17 So for my specific question that I set 18 out to answer, I don't believe any -- I mean, 19 if there -- if there was any specific modeling 20 data, I would have looked at it. But I don't 21 believe that would negate looking at studies 22 that looked at -- at those responses. 23 And by the way, the Hidajat studies 24 did quite a sophisticated dose response 25 analysis. So, again, I -- I don't quite</p>

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<p>1 understand what these authors are -- are</p> <p>2 referring to when they're talking about</p> <p>3 modeling, because statistical dosing modeling</p> <p>4 was done in some of the studies that I</p> <p>5 included.</p> <p>6 BY MR. FOWLER:</p> <p>7 Q I want to show you the paragraph that</p> <p>8 starts, "Biological gradient." It's just down below</p> <p>9 this box.</p> <p>10 Doctor, "Biological gradient is an</p> <p>11 example of how data integration can complicate</p> <p>12 causal inference." Do you agree with that</p> <p>13 description of the Bradford Hill criteria,</p> <p>14 biologic -- biological gradient?</p> <p>15 A Yes.</p> <p>16 Q And if you look three lines -- strike</p> <p>17 that.</p> <p>18 The next sentence, "New tools and</p> <p>19 technical capabilities have allowed researchers to</p> <p>20 characterize a variety of low level molecular end</p> <p>21 points that may not lead to disease or observable</p> <p>22 outcomes on a larger scale."</p> <p>23 Did I read that correctly, Doctor?</p> <p>24 A Yes, I'm just rereading it.</p> <p>25 Q Yes, sir.</p>	<p>1 level?</p> <p>2 MR. NIGH: Form objection.</p> <p>3 THE WITNESS: I think threshold dose</p> <p>4 levels are a very technical, specific question</p> <p>5 with respect to NDMA and cancer. The more</p> <p>6 general question that's sort of the umbrella</p> <p>7 question that I was set up to look at was,</p> <p>8 generally speaking, does exposure to NDMA over</p> <p>9 a long period cause cancer. And I don't</p> <p>10 believe that you need -- I mean, they were --</p> <p>11 statistical modeling was used in the studies.</p> <p>12 But I don't -- I don't think you specifically</p> <p>13 need sophisticated tools or modelings to set</p> <p>14 out the question that I -- that I wanted to</p> <p>15 answer.</p> <p>16 BY MR. FOWLER:</p> <p>17 Q Well, Doctor, looking at the first</p> <p>18 part of this criteria five, it states that</p> <p>19 Sir Bradford Hill -- it says, "However, Hill</p> <p>20 acknowledged that more complex dose relationships</p> <p>21 may exist."</p> <p>22 Did you consider that when trying to</p> <p>23 evaluate the biological gradient for NDMA, sir?</p> <p>24 MR. NIGH: Form objection.</p> <p>25 THE WITNESS: Again, I did not have,</p>
Page 114	Page 116
<p>1 And it says further down, "Thus</p> <p>2 molecular changes within the no observable adverse</p> <p>3 effect level may not contribute to disease and are</p> <p>4 more indicative of a threshold dose."</p> <p>5 Doctor, with that backdrop, did you</p> <p>6 make any attempt to determine whether there is a no</p> <p>7 observable effects level for low doses of NDMA or</p> <p>8 NDEA?</p> <p>9 MR. NIGH: Form objection.</p> <p>10 THE WITNESS: Again, that wasn't the</p> <p>11 question that I set out to answer. The</p> <p>12 question that I set out to answer was -- was</p> <p>13 exposure to NDMA over a long period of time,</p> <p>14 high dose versus low dose, has a differential</p> <p>15 risk of cancer. What they're talking about</p> <p>16 here are -- again, they don't really specify</p> <p>17 the type of studies, the type of exposure. I</p> <p>18 think they're making very -- very general</p> <p>19 statements on the very large sort of scope of</p> <p>20 topics.</p> <p>21 BY MR. FOWLER:</p> <p>22 Q And do you believe, Doctor, that the</p> <p>23 biological gradient of the Bradford Hill criteria</p> <p>24 can be satisfied when evaluating NDMA and NDEA</p> <p>25 without an understanding of any threshold dose</p>	<p>1 you know, data on NDMA gradient or doses.</p> <p>2 My -- my question was to look at the literature</p> <p>3 and answer the question whether long-term</p> <p>4 exposure to NDMA causes cancer. Again, I go</p> <p>5 back to what I mentioned a few minutes --</p> <p>6 seconds ago.</p> <p>7 BY MR. FOWLER:</p> <p>8 Q Yes, sir.</p> <p>9 A Your -- your question I believe is</p> <p>10 looking at a more specific type of a question.</p> <p>11 For a general causation question, I do</p> <p>12 not believe that -- and, again, with Bradford Hill's</p> <p>13 statement here, which is very general, I do not</p> <p>14 believe that for the question that I set out to do,</p> <p>15 I needed that information that you mentioned.</p> <p>16 Q Thank you.</p> <p>17 MR. FOWLER: I have nothing further,</p> <p>18 sir. I think we have left some time remaining</p> <p>19 for any follow-up questions. Thank you for</p> <p>20 your time over these two days. I appreciate</p> <p>21 it.</p> <p>22 THE WITNESS: Thank you.</p> <p>23 MR. NIGH: Do we have anybody else</p> <p>24 that's asking questions on the defense side?</p> <p>25 Steven, do you know?</p>

<p style="text-align: right;">Page 117</p> <p>1 MR. FOWLER: No, sir. I don't believe 2 we do. 3 MR. NIGH: Okay. Can we get a -- are 4 we on the record, or can we go off the record? 5 THE VIDEOGRAPHER: Yes. The time is 6 now 11:09. We're going off the record. 7 (Whereupon, a short break was taken.) 8 THE VIDEOGRAPHER: The time is now 9 11:27. We're back on the record. 10 MR. NIGH: Steven, this is -- in 11 response to your question earlier about not 12 being on camera, I didn't want to be short with 13 you, and I did want to give you a reason. My 14 daughter has been -- was diagnosed with COVID 15 about a week and a half ago. I think that's 16 the timing. And so, frankly, I have had to 17 do -- and defend the deposition remotely. So I 18 don't have the same sort of bandwidth that I 19 have in my office. And with that, we have had 20 some storms that have rolled through both 21 yesterday and today. And when I'm on -- not on 22 video, but just speaking, then it doesn't have 23 as much breakup. 24 So I think right now, it's probably 25 okay. The weather is a little bit better</p>	<p style="text-align: right;">Page 119</p> <p>1 MR. GALLAGHER: Duane Morris would 2 like a copy. I think we're already set up to 3 get one, but just in case. 4 MR. HARKINS: Same for 5 Greenberg Traurig. If you don't have an order 6 for us, we certainly want a copy. 7 MS. KAPKE: Jamie, this is Kara from 8 CVS and Rite Aid. I'll take a copy, just 9 regular delivery, etrans. 10 MR. TRISCHLER: This is Clem Trischler 11 from Mylan. I think we have -- we should have 12 a standing order for all depositions, so we 13 would want that. But if we don't, or if you 14 don't have that, we do want a copy. 15 THE COURT REPORTER: Counsel, anyone 16 else? 17 MR. SHAH: This is Nakul Shah for 18 Hetero Drugs and Hetero Labs. We would like a 19 final version of the transcript as well. 20 THE COURT REPORTER: Okay. Anything 21 else, counsel? 22 (Whereupon, the deposition concluded 23 at 11:27 a.m.) 24 25</p>
<p style="text-align: right;">Page 118</p> <p>1 outside, but I figured I'd give you that 2 explanation since you asked. And I know that 3 we have had, you know, multiple other past 4 depositions where the one making objections has 5 not appeared on camera. 6 MR. FOWLER: Thank you. And best 7 wishes for you daughter's recovery. I'm sorry 8 to hear that. 9 MR. NIGH: Yes, thank you. 10 At this time, we do -- we're not going 11 to ask any questions, and so I'd like to thank 12 Dr. Etminan for his time. And I think that 13 this time, you're free to go. Thank you. 14 THE VIDEOGRAPHER: The time is now 15 11:27. This ends today's deposition. Thank 16 you. Thank you all. 17 THE COURT REPORTER: Counsel, does 18 anybody want copies? 19 MR. NIGH: We will want one copy. It 20 can come to me on the plaintiff's side, I don't 21 know if you have my information already -- and 22 then we do want a -- we do want to read the 23 transcript -- 24 THE COURT REPORTER: Sure. 25 Any other counsel?</p>	<p style="text-align: right;">Page 120</p> <p>1 C E R T I F I C A T E 2 3 I, Jamie I. Moskowitz, a Shorthand 4 (Stenotype) Reporter and Notary Public, do hereby 5 certify that the foregoing Deposition, of the 6 witness, MAHYAR ETMINAN, taken at the time and place 7 aforesaid, is a true and correct transcription of my 8 shorthand notes. 9 I further certify that I am neither 10 counsel for nor related to any party to said action, 11 nor in any way interested in the result or outcome 12 thereof. 13 IN WITNESS WHEREOF, I have hereunto set 14 my hand this 2nd day of September, 2021. 15 16 <%1154,Signature%> 17 Jamie Ilyse Moskowitz 18 License No. XI01658 19 20 21 22 23 24 25</p>

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1 Daniel A. Nigh, Esq.
 2 dnigh@levinlaw.com
 3 September 2, 2021.
 4 RE: In Re: Valsartan, Losartan, Et Al v.
 5 8/25/2021, Mahyar Etminan (#4772413)
 6 The above-referenced transcript is available for
 7 review.
 8 Within the applicable timeframe, the witness should
 9 read the testimony to verify its accuracy. If there are
 10 any changes, the witness should note those with the
 11 reason, on the attached Errata Sheet.
 12 The witness should sign the Acknowledgment of
 13 Deponent and Errata and return to the deposing attorney.
 14 Copies should be sent to all counsel, and to Veritext at
 15 cs-ny@veritext.com.
 16
 17 Return completed errata within 30 days from
 18 receipt of testimony.
 19 If the witness fails to do so within the time
 20 allotted, the transcript may be used as if signed.
 21
 22 Yours,
 23 Veritext Legal Solutions
 24
 25

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1 In Re: Valsartan, Losartan, Et Al v.
 2 Mahyar Etminan (#4772413)
 3 ACKNOWLEDGEMENT OF DEPONENT
 4 I, Mahyar Etminan, do hereby declare that I
 5 have read the foregoing transcript, I have made any
 6 corrections, additions, or changes I deemed necessary as
 7 noted above to be appended hereto, and that the same is
 8 a true, correct and complete transcript of the testimony
 9 given by me.
 10
 11 _____
 12 Mahyar Etminan Date
 13 *If notary is required
 14 SUBSCRIBED AND SWORN TO BEFORE ME THIS
 15 _____ DAY OF _____, 20____.
 16
 17
 18 _____
 19 NOTARY PUBLIC
 20
 21
 22
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1 In Re: Valsartan, Losartan, Et Al v.
 2 Mahyar Etminan (#4772413)
 3 E R R A T A S H E E T
 4 PAGE _____ LINE _____ CHANGE _____
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 18 REASON _____
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 23 _____
 24 Mahyar Etminan Date
 25

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